

Cahoy Dec. Ex. 75

**UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA**

SURGICAL INSTRUMENT SERVICE
COMPANY, INC.,

Plaintiff and
Counter-defendant,

vs.

INTUITIVE SURGICAL, INC.,

Defendant and
Counterclaimant.

Case No.: 3:21-cv-03496-VC

Expert Report of Dr. Robert D. Howe
OUTSIDE COUNSEL ONLY—SUBJECT TO PROTECTIVE ORDER

January 18, 2023

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I. Qualifications

1. I received a Ph.D. in Mechanical Engineering from Stanford University in 1990, a Masters in Mechanical Engineering from Stanford University in 1985, and a Bachelor degree in Physics from Reed College in 1979. Prior to attending graduate school I worked in Silicon Valley as an electronics engineer, designing analog and digital electronics. Since receiving my doctorate, I have devoted my professional career to the research, design, development, study, and teaching of numerous aspects of mechanical and bioengineering.

2. I am currently the Abbott and James Lawrence Professor of Engineering at the Harvard Paulson School of Engineering and Applied Sciences. I serve as the founding co-chair of the Harvard MS/MBA degree program, a joint effort of Harvard's engineering and business schools aimed at training leaders in commercialization of technology. I am also a core faculty member of the Harvard-MIT Division of Health Sciences and Technology, a premier biomedical graduate training program. In 1990, I founded the Harvard BioRobotics Laboratory, which investigates the roles of sensing and mechanical design and motor control in both humans and robots. I have taught numerous courses at Harvard ranging from entry-level mechanical engineering courses to graduate-level robotics and bioengineering seminars. In 2007, I was elected Fellow of the American Institute for Medical and Biological Engineering, and in 2012, I was elected Fellow of the Institute of Electrical and Electronic Engineers. I have held visiting and adjunct scientist or professor positions at the Massachusetts Institute of Technology, Stanford University, Tufts University, and several foreign institutes and universities.

3. I am a named inventor on nine patents involving robotic and medical device technology and am the author or co-author of over 200 peer-reviewed technical publications.

4. I provided expert testimony in *Rebotix Repair LLC v. Intuitive Surgical, Inc.* and *Restore Robotics LLC and Restore Robotics Repair v. Intuitive Surgical, Inc.* In both cases, I

submitted expert reports on: (1) differences between EndoWrist instruments and traditional laparoscopic instruments; (2) Intuitive's design control and risk management processes for EndoWrist instruments; (3) Intuitive's life testing of EndoWrist instruments; (4) the "EndoWrist Service Procedure" employed by Rebotix and Restore, respectively; (5) Rebotix's risk management activities; and (6) Rebotix's life testing. In *Restore Robotics*, my expert report also discussed Restore's "service" procedures for da Vinci surgical systems. I also provided a supplemental expert report in *Restore Robotics* discussing the FDA's recent clearance of Iconocare Health's 510(k) application, which permits Iconocare to market a remanufactured S/Si 8mm Monopolar Curved Scissor instrument reset one time with ten additional lives (for a total of up to 19).

5. I previously submitted an expert report in this case on: (1) differences between EndoWrist instruments and traditional laparoscopic instruments; (2) the "EndoWrist Service Procedure" employed by Rebotix on behalf of SIS; (3) SIS's assumption that Rebotix's service procedure is safe and reliable; (4) SIS's reliance on Rebotix's risk management and life testing; and (5) Rebotix's risk management activities and life testing. Those opinions are incorporated by reference into this Report.

6. My education and experience in these fields are set forth in detail in my attached curriculum vitae, attached as Appendix A of this Report, which includes a list of publications authored in the previous 10 years and a list of all other cases in which I have testified or been deposed in the past four years.

II. Assignment

7. I have been retained by counsel from the law firm Skadden, Arps, Slate, Meagher & Flom LLP on behalf of its client, Intuitive Surgical, Inc. ("Intuitive"), concerning a dispute between Intuitive and Surgical Instrument Service Company, Inc. ("SIS"). In particular, I have

been asked to provide opinions on the safety and reliability of the services performed by third parties on EndoWrists and the Intuitive systems. This includes responding to certain opinions offered in the expert reports of Richard Bero, Russell Lamb, Amandeep Mahal, and Philip Phillips, provided in support of Plaintiff's claims. My general understanding of the dispute as it relates to my Report and analysis is as follows.

8. Intuitive designs, manufactures, and markets the da Vinci robotic-assisted surgical system ("da Vinci"), along with its associated instruments, including EndoWrist instruments, for use in minimally invasive surgery. Certain da Vinci instruments, such as EndoWrist instruments, incorporate a usage limit on the number of procedures that can be performed, after which the instrument must be replaced. As Intuitive explains in its Answer and Counterclaims, the usage limits "are determined through a rigorous process involving substantial scientific testing and analysis" to ensure EndoWrist instruments are "safe, reliable and efficacious."² And as described further below, Intuitive's usage limits "are critical for patient safety, designed in compliance with FDA regulations, requirements and publications, consistent with applicable industry standards as well as EndoWrist labeling and amply supported and validated by scientific testing."³

9. SIS is a third party that has offered certain services in connection with da Vinci robotic-assisted surgical systems, including for certain EndoWrist instruments that can be used with the S and Si da Vinci Surgical systems.⁴ SIS facilitated for its customers a "reset service"

Defendant Intuitive Surgical, Inc.'s Counterclaims, ¶ 29 (filed Dec. 14, 2021).

² *Id.* ¶ 27.

³ *Id.* ¶ 13.

⁴ EndoWrist Instruments that can be used with Intuitive's S and Si da Vinci systems are often referred to as S and Si instruments. In addition, most of Intuitive's internal engineering and

that bypasses the original usage limits of EndoWrist instruments to enable end-users to keep using the EndoWrist instruments beyond those built-in limits. [REDACTED]

[REDACTED]

[REDACTED] Rebotix is able to bypass Intuitive’s usage counter by inserting a “Rebotix Interceptor” into EndoWrist instruments, which according to Rebotix, resets the usage counter. In its Complaint, SIS alleges that “[a]fter service by SIS, the surgical device or instrument is returned to the customer for its original intended use . . . and the surgical device or instrument is returned to its original safety and effectiveness.”⁷ But as Intuitive explains in its Counterclaims, Rebotix’s insertion of the Interceptor “override[s] a fundamental feature of EndoWrists, significantly changing their intended use and their performance and safety specifications.”⁸ [REDACTED]

technical documents refer to the S and Si systems as the IS2000 and IS3000 systems and refer to the EndoWrist instruments as IS2000 and IS3000 instruments, respectively.

⁵ Oct. 27, 2022 Keith Johnson 30(b)(6) Tr. at 33:22-34:2 [REDACTED]

⁶ Oct. 27, 2022 Keith Johnson 30(b)(6) Tr. at 33:25-34:4.

⁷ SIS Complaint, ¶ 33 (filed May 10, 2021).

⁸ Defendant Intuitive Surgical, Inc.’s Counterclaims, ¶ 48 (filed Dec. 14, 2021).

⁹ Oct. 27, 2022 Keith Johnson 30(b)(6) Tr. at 22:10-11.

[REDACTED]

[REDACTED]

10. Another third party, Restore Robotics LLC (collectively with its related entity Restore Robotics Repairs LLC, “Restore”) also offered certain services in connection with da Vinci robotic-assisted surgical systems, including for EndoWrist instruments that can be used with the S and Si da Vinci Surgical systems. Like SIS, Restore offered a “service” that bypassed the original usage limits of EndoWrist instruments, utilizing the Interceptor technology developed by Rebotix, so that end-users could continue using EndoWrist instruments beyond those built-in limits. In addition to bypassing the usage limits on EndoWrist instruments, Restore also offered to customers servicing of the da Vinci robotic surgical system. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].²

11. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED],³ [REDACTED]

[REDACTED].”

[REDACTED]

[REDACTED]

[REDACTED]

³ Restore-00089490 at Restore-00089492 93 [REDACTED]

[REDACTED]

12. I was asked to review the record information in this matter regarding Intuitive's mechanical design of the EndoWrist instruments and the scientific testing performed to validate the EndoWrist usage limits. I was also asked to review the available information regarding the development of the Rebotix Interceptor, the installation of the Rebotix Interceptor, and any testing (or lack of testing) that Restore, Rebotix, or SIS performed to determine whether bypassing the EndoWrist's usage limits was mechanically viable or safe and reliable for patient use. Finally, I was asked to review information regarding the Iconocare Process, and assess any differences between the Restore/Rebotix Process and the Iconocare Process, as well as the risk management and life data supporting each process.

13. What follows is a Report on my findings after a review of the relevant materials, which were identified through an examination of documents produced in the litigation, SIS's Complaint (ECF No. 1) ("SIS Complaint"), Defendant Intuitive Surgical, Inc.'s Answer, Affirmative Defense and Counterclaims (ECF No. 75), a review of testimony provided by witnesses at deposition, and a review of SIS's written discovery responses. A list of materials I considered in connection with this matter is attached as Appendix B of this Report.

14. I am being compensated for my work at the rate of \$600 per hour. My compensation is in no way dependent on the outcome of this matter. Additional time required for trial testimony or deposition will also be billed at the rate of \$600. I was supported in this matter by a postdoctoral research associate in the Harvard Paulson School of Engineering and Applied Sciences, Dr. Richard Nuckols, who was compensated for his work at the rate of \$125 per hour.

III. Summary of Opinions

15. It is my opinion that there are significant differences between EndoWrist instruments and traditional laparoscopic instruments, and that these differences contribute to EndoWrist instruments having a shorter useful life than traditional laparoscopic instruments. Unlike traditional laparoscopic instruments, EndoWrists have a set of mechanical joints (or “wrists”) at their distal end ⁴ which permit three degrees of freedom of movement (as compared to one or at most two degrees of freedom in typical traditional laparoscopic instruments). These additional degrees of movement in EndoWrists are made possible by the use of cables and pulleys within the instrument. While the cable and pulley mechanisms utilized by EndoWrist instruments permit additional degrees of movement and dexterity, they are less durable and more prone to mechanical failure over an extended period of use than the drive rods typically utilized in traditional laparoscopic instruments. There is thus a tradeoff whereby EndoWrist instruments permit increased dexterity and freedom of motion but fewer uses as compared to traditional laparoscopic instruments.

16. It is my opinion that Intuitive maintains rigorous design control and risk management processes which illuminate, and allow Intuitive to account for, the various risks or potential failure modes associated with the EndoWrist instruments. Intuitive’s comprehensive design control processes allow Intuitive to design instruments so as to support reliable and consistent performance over a prescribed number of uses.

⁴ The distal end, as the term is used regarding EndoWrist instruments, is the portion of the instrument that interacts with the patient to perform a function during a surgical procedure. The other end, referred to as the proximal end, is the portion of the instrument that connects to the da Vinci surgical system.

17. It is my opinion that Intuitive’s rigorous testing of its EndoWrist instruments adequately reflects the stresses and forces that instruments are subjected to during clinical use and demonstrates that instruments can only be reliably used a limited number of times. Both Intuitive’s life testing and actual, clinical results demonstrate that EndoWrist instruments experience significant wear and tear during their prescribed useful life.

18. It is my opinion that although Rebotix, Restore, and SIS refer to the “reset” services as a “repair,”⁵ Rebotix simply devised a method that intercepts communication between the robot and the instrument in order to circumvent the usage limits implemented in each EndoWrist instrument, without adequately addressing the effects of wear and tear that accrue during instrument usage.

19. [REDACTED]
[REDACTED]. The steps performed during the Rebotix Process fail to adequately address many of the risks associated with extending the number of times an EndoWrist instrument may be used beyond the prescribed usage limit, such as the risks of mechanical failure by components within the instrument’s proximal housing. This increased risk of failure would not necessarily be evident based on a visual inspection of the instrument by a surgeon or hospital staff. Moreover, there are numerous ways the Rebotix Process may introduce additional risks to instrument functionality and increase the likelihood of the failure modes identified by Intuitive during their own life testing.

⁵ [REDACTED]

⁶ See REBOTIX162404 (described *infra* § VI.A).

⁷ See Restore-00001538.

20. It is my opinion that Rebotix's risk management activities with respect to extending the lives of EndoWrist instruments are inadequate. Rebotix's risk management activities with respect to extending the life of the EndoWrist instruments assume that the Rebotix servicing procedure is adequate to restore the instruments to equivalent specifications to new instruments, but do not consider the deleterious effects of previous surgical uses and sterilization procedures, which have been clearly shown to decrease reliability. In addition, they do not adequately address the risks of mechanical failure associated with using an EndoWrist instrument beyond the prescribed usage limit.

21. It is my opinion that Rebotix's life testing fails to adequately simulate the stresses and forces that instruments are subjected to during clinical use and therefore cannot reliably be said to validate the use of the EndoWrist instruments for uses beyond the prescribed usage limit.

22. It is my opinion that Restore and SIS relied entirely on Rebotix's risk management activities and life testing, and that the limited information available to them was not sufficient to determine whether the instrument was safe or reliable.

23. It is my opinion that Intuitive's position that it could potentially develop robust EndoWrist refurbishment procedures does not mean that Rebotix's resetting procedures were adequate.

24. It is my opinion that there are significant differences between the Rebotix Process for remanufacturing S/Si EndoWrist instruments and the Iconocare Process for remanufacturing the S/Si 8mm Monopolar Curved Scissor EndoWrist, and the Iconocare Process is likely to produce safer and more reliably-remanufactured instruments than the Rebotix Process.

25. It is my opinion that the risk management and life data submitted to the FDA for the Iconocare Process is significantly more robust than the risk management and life testing data Rebotix had access to in connection with the Rebotix Process.


26. It is my opinion that, while even a single EndoWrist reset introduces safety risks, there are significantly greater safety risks created by resetting an EndoWrist usage counter multiple times (as Restore and Rebotix claimed they could do with their processes) than by resetting the usage counter once (as called for by the Iconocare Process).

27. Discovery is ongoing in this matter, and I reserve the right to amend or supplement my opinions and findings as additional material becomes available.

IV. The Intuitive EndoWrist Instrument and the Interceptor

A. Overview of Intuitive S/Si EndoWrist Instruments

28. EndoWrist instruments are designed for use in conjunction with the da Vinci surgical robot system. I first became aware of the EndoWrist instrument design through conversations with Dr. Ken Salisbury and Akhil Madhani, his doctoral student at MIT, soon after they invented these instruments in the mid-1990's. After their invention, I have had many EndoWrist instruments in my lab, which we analyzed as part of our research efforts on new surgical instrumentation. I have also had many opportunities to operate various models of the da Vinci robot, including an extended collaboration with surgeons at Boston Children's Hospital, where they had a robot dedicated to training and research that afforded me and my research group opportunities to perform experiments on sensing and control using the robot.

29. EndoWrist instruments are endoscopic instruments that access tissues within the patient's body through small incisions in order to minimize damage to healthy tissue. In contrast to conventional manually-driven endoscopic (laparoscopic) instruments, EndoWrist instruments have a set of mechanical joints located at the distal end. *See Figure 1.* 

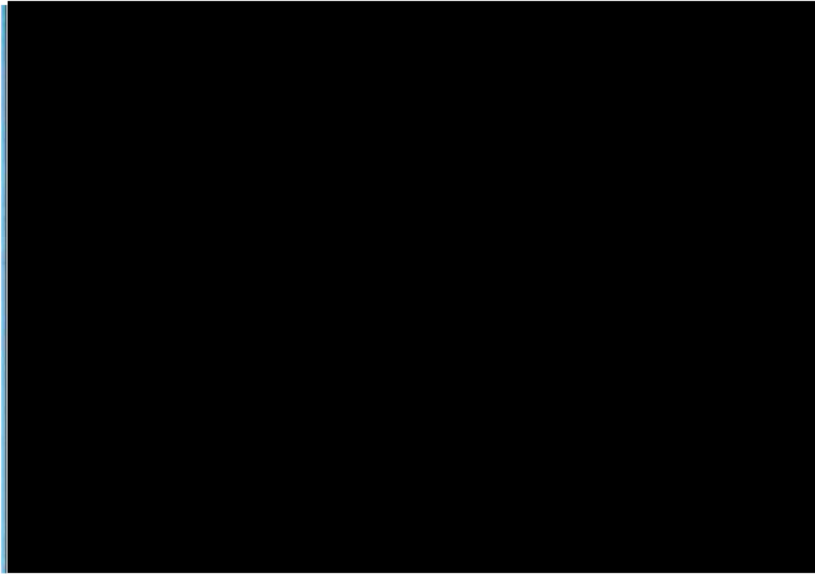
[REDACTED]

[REDACTED]

30. To provide the additional degrees of freedom at the surgical site compared to traditional laparoscopic instruments, EndoWrist instruments use a sophisticated cable drive mechanism. This innovative system was the subject of several issued US and international patents.⁹ Four input pulleys on the proximal end of the instrument mate with motor drives in the surgical robot. These pulleys are connected to internal cables that control roll of the instrument shaft, yaw and pitch of the instrument wrist, and open/close of the end effector. These cables pass over idler pulleys, then through the elongated instrument shaft to the wrist, where they are routed over a series of pulleys to produce the intended motion. Inside the central length of the shaft, the cables are crimped onto rods to reduce the effects of cable stretch, but the cables wrap around pulleys in both the proximal and distal ends of the instrument. In addition to allowing the required degrees of freedom to fit within the constrained shaft diameter, the use of cables also enables a large range of motion in each degree of freedom.

⁸ See [REDACTED]

⁹ See, e.g., US Patent Nos. 5,797,900 (“Wrist Mechanism for Surgical Instrument for Performing Minimally Invasive Surgery with Enhance Dexterity and Sensitivity”) and 6,991,627 (“Articulated Surgical Instrument for Performing Minimally Invasive Surgery with Enhanced Dexterity and Sensitivity”).



*Figure 1.*²⁰

31. An essential part of the specifications for the EndoWrist instruments is a limitation on the number of times each instrument can be used for surgical procedures.² In S and Si instruments, the limitation is implemented through an integrated circuit that keeps track of the number of times the instrument is used in a surgical procedure by a da Vinci robot. This chip, a Maxim/Dallas Semiconductor DS2505 (sometimes referred to as the “Dallas chip”) resides on a small printed circuit board in the proximal housing of each instrument. It is an add-only memory that communicates with the robot over a one-wire bus, where additional data can be programmed

²⁰

² As described further below, the specifications for EndoWrist instruments are detailed in a series of documents, which include Architectural Requirement Documents (“ARDs”) and Functional Requirements Documents (“FRDs”), among others. The ARD for the IS1200, IS2000 and IS3000 Instruments provide that the instruments “shall be programmed with the number of uses as specified in the individual Instrument Functional Requirements.” Intuitive-00538487 at Intuitive-00538496. The FRDs contain the specific requirements for individual instruments and set out the maximum number of times each type of instrument may be used. *See* Intuitive-00539807.

into EPROM without disturbing existing data, and each memory page can be permanently write-protected to prevent tampering. In addition, each chip has a unique factory-set serial number.²² These features provide a secure means for keeping track of the number of uses. During manufacturing, the DS2505 chip is programmed with the total number of allowed uses; for most S and Si EndoWrist instruments, this usage limit is ten surgical procedures.²³ When an instrument is connected to a da Vinci robot, the robot's controllers communicate with the chip over the one-wire bus via a pogo pin connector in the proximal housing. The robot queries the chip for stored information, including the number of previous uses. If the uses have been decremented to zero, the robot will not activate the instrument. [REDACTED]

[REDACTED] In X/Xi instruments, the usage limitation is implemented through an RFID chip that communicates the use counter information and other data from the EndoWrist to the da Vinci system itself.²⁵

B. Differences Between Intuitive EndoWrist Instruments and Traditional Laparoscopic Instruments

32. SIS alleges in its Complaint that EndoWrist instruments are “substantially identical to similar instruments used in traditional surgeries.”²⁶ SIS also alleges that “EndoWrist instruments are suitable for many more uses” than their original use limits.²⁷ [REDACTED]

²² See DS2505 Dallas Semiconductor data sheet, available at: <https://datasheets.maximintegrated.com/en/ds/DS2505.pdf>; see also Intuitive-00538487 at Intuitive-00538496 (describing Dallas Chip Interface Requirements for EndoWrist instruments).

²³ See Intuitive-00539807 (FRD) (setting out usage limits).

²⁴ [REDACTED].

²⁵ Nov. 8, 2022 Grant Duque 30(b)(6) Tr. at 22:5 23:17; Nov. 4, 2022 Sharathchandra Somayaji Tr. at 108:18 109:22.

²⁶ SIS Complaint, ¶ 27 (filed May 10, 2021).

²⁷ *Id.* ¶ 35.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]⁰ I disagree.

33. Traditional endoscopic instruments differ in essential ways from EndoWrist instruments. I have observed the use of traditional endoscopic instruments in dozens of laparoscopic and thoracoscopic surgical procedures, and my lab has analyzed their design and function as part of our own efforts to develop minimally invasive surgical instrumentation. Both traditional endoscopic and EndoWrist instruments have an elongated shaft to enable surgeons to work through a small incision. However, both the proximal and distal ends of EndoWrist instruments are significantly different than traditional endoscopic instruments, as is the mechanical connection between the ends. At the proximal end, traditional instruments have handles (typically a pair of levers or finger loops), which surgeons hold in their hands to apply forces and motions to the instrument and to open and close an end effector like scissor blades or forceps jaws (typical examples are shown in Figure 2). In contrast, EndoWrist instruments connect to a set of motor drives through four pulleys. *See* Figure 3.

²⁸ Oct. 27, 2022 Keith Johnson 30(b)(6) Tr. at 24:20-21, 26:5-9.

²⁹ Expert Report of Amandeep Mahal (Dec. 1, 2022) (“Mahal Rep.”), ¶ 65.

³⁰ Expert Report of Russell Lamb (Dec. 2, 2022) (“Lamb Rep.”), ¶ 130.

34. The motor interface of an EndoWrist instrument introduces a number of constraints and potential failure modes to the instrument design that are not present in manual instruments. Examples of failures identified and considered by Intuitive engineers in designing the EndoWrist instruments include the possibility that the pins (or “dogs”) on the input pulleys would slip or shear off, potentially resulting in loss of control of the instrument.³ Similarly, the bearings that enable low-friction motion of the input pulleys and shafts can fail, potentially resulting in loss of instrument functionality and/or having the bearings or their fragments fall into the patient.³² There are no analogous parts to these two examples in conventional endoscopic surgical instruments. Additional examples of potential failures that pertain to the motor interface of EndoWrist instruments are detailed by Intuitive through their design control and risk assessment process.³³

³ See, e.g., Intuitive-00538994 at Tab 10, Rows 17-18.

³² See, e.g., *id.* at Tab 11, Row 11.

³³ See generally *id.*



35. EndoWrist instruments have unique capabilities that are not available with conventional endoscopic instruments. In particular, the wrist mechanism provides three degrees of freedom at the end of the instrument, often referred to as wrist yaw, wrist pitch, and grip. This contrasts with conventional endoscopic instruments that typically have one or at most two

³⁴ “Access and instruments product catalog” Medtronic, 2020, available at: <https://www.medtronic.com/content/dam/covidien/library/us/en/product/hand-instruments-and-ligation/access-instrumentation-products-catalog.pdf>.

³⁵ [REDACTED]

degrees of freedom. This provides the dexterity that allows surgeons using the da Vinci robot to perform some minimally invasive surgical procedures that are difficult or impossible to perform with conventional endoscopic instruments. While some manual instrument designs have attempted to provide additional degrees of freedom at the distal end, these have proved difficult to control in a dexterous manner; typically, an extra degree of freedom in tip orientation is manually set to a specific angle and left unchanged during subsequent maneuvers. The combination of the difficulty of control of additional degrees of freedom as well as their increased costs means that traditional endoscopic instruments do not provide the motion capabilities that EndoWrist instruments deliver. In contrast, the relative simplicity of conventional endoscopic instruments means that they can use much simpler, more robust, and less expensive drive mechanisms to fit in the constraints of shaft diameter. By far the most common design uses push-pull drive rods that pass through the instrument shaft to operate the distal degree(s) of freedom. These mechanisms are simple to design and are robust because they operate in simple loading conditions that are accurate to model during design and robust during operation, in contrast to the cable drives in EndoWrist instruments. As a result, traditional instruments are more resilient to fatigue, corrosion, and wear.³⁶

36. Because the EndoWrist instruments are driven by motors under computer control, they are also subject to high forces due to collisions that are not present for manual instruments. When a surgeon uses the control inputs to command an instrument to move along a path that intersects with another instrument, the ensuing collision can prevent the instrument from going to the commanded location. The instrument controllers can then generate high motor

³⁶ Richard G. Budynas and J. Keith Nisbett, *Shigley's Mechanical Engineering Design*, Ninth Edition, McGraw-Hill, New York, 2008, Chapters 3-5.

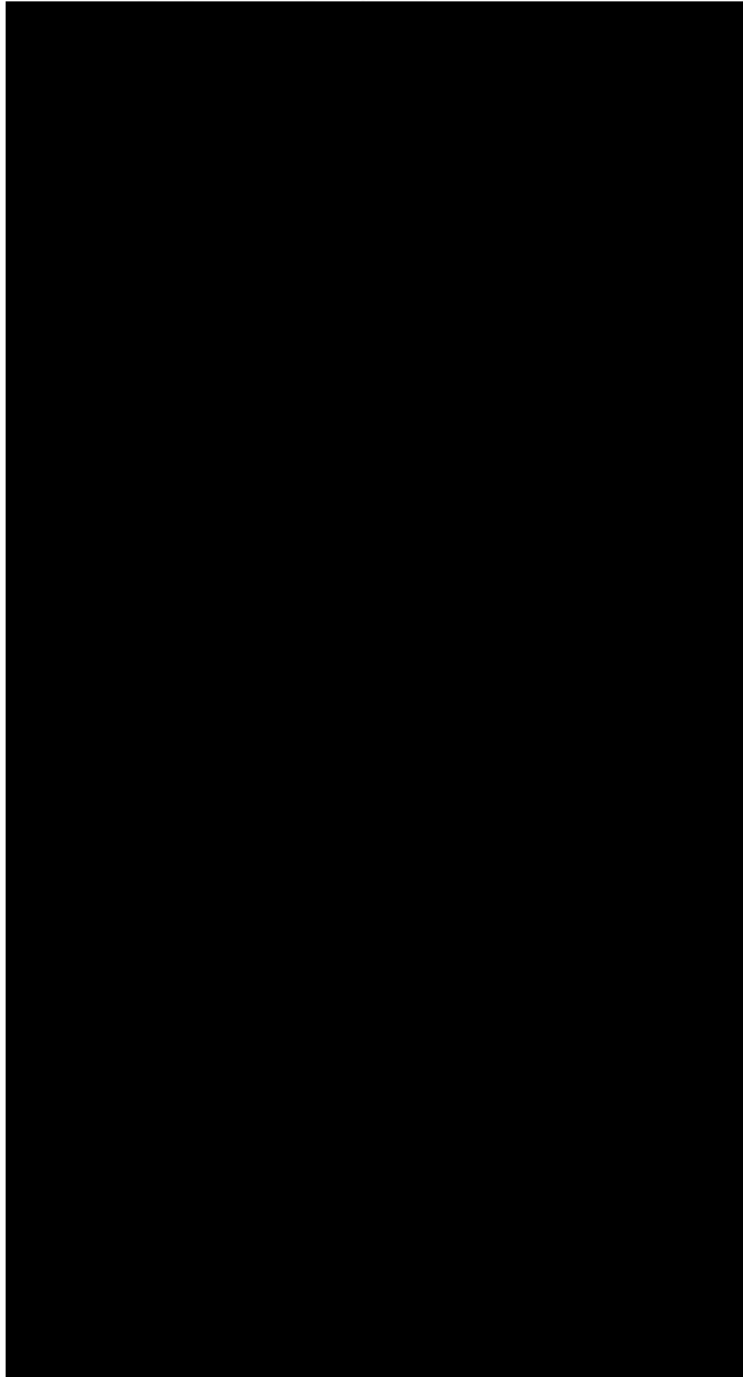
forces in an attempt to move the instrument as commanded, resulting in high forces applied to the instrument, particularly the wrist. This type of interaction is not present for manual laparoscopic instruments, where instrument motions are directly generated by the surgeon's hands and collisions result in far lower forces.

37. Unlike drive rods, cable drives (often alternatively referred to as “wire rope drives”) are more complex to design, particularly for high reliability across product life. Designers of wire cable or rope drives frequently focus on wear and fatigue issues. For example, a leading textbook on mechanical design elucidates these issues in the context of the interaction between the rope and the pulleys (or “sheaves”) over which it passes:

Once you have made a tentative selection of a rope based upon static strength, the next consideration is to ensure that the wear life of the rope and the sheave or sheaves meets certain requirements. When a loaded rope is bent over a sheave, the rope stretches like a spring, rubs against the sheave, and causes wear of both the rope and the sheave . . . The allowable pressures given in Table 17-26 are to be used only as a rough guide; they may not prevent a fatigue failure or severe wear. They are presented here because they represent past practice and furnish a starting point in design. . . . In view of the fact that the life of wire rope used over sheaves is only finite, it is extremely important that the designer specify and insist that periodic inspection, lubrication, and maintenance procedures be carried out during the life of the rope.³⁷

38. The EndoWrist design is particularly challenging because of its small size and multiple degrees of freedom. *See* Figure 4.

³⁷ Richard G. Budynas and J. Keith Nisbett, *Shigley's Mechanical Engineering Design*, Ninth Edition, McGraw- Hill, New York, 2008, Chapter 7, pp. 919-921.



[REDACTED]

The result is that the cables pass over multiple pulleys in alternating directions. This is known to reduce the life of the cables:



Figure 4-8. Reverse Bend

To maximize the service life of a wire rope, it should be reeved (or threaded) through a block and tackle system with a minimum number of sheaves and the fewest possible reverse bends. Reverse bends, as shown in Figure 4-8, occur when the rope bends over a sheave in one direction, then under another in the opposite direction within a distance short enough so that a section of the rope traverses both sheaves. Bending fatigue due to this condition will reduce life to half of that experienced with only single-direction bends.³⁹

39. The cleaning and sterilization cycles to which EndoWrist instruments are repeatedly subjected are particularly detrimental to continuing reliable operation. Intuitive documents describe the impact on reliability of these reprocessing cycles. For example:

Ideally, the number of instrument uses is equal to its number of reprocessing cycles. However, depending on the practices of a hospital, instruments may undergo more reprocessing cycles than they do uses. Number of uses can be different from the number of reprocessing cycles when an instrument is brought into a sterile field, but is not put on the system and used by the surgeon. The instrument would still need to be reprocessed because it became contaminated by the surgical field, but, since the system-instrument interaction is what deducts the number of instrument lives, the number of uses remaining would remain unchanged. Current reliability testing accounts for these additional reprocessing cycles by testing to 5 additional reprocessing cycles to the

³⁹ U.S. Navy Wire-Rope Handbook, Vol. 1, p. 4-11.

Weibull analysis. When the number of reprocessing cycles far outnumber the number of uses, early failures can occur.⁴⁰

40. The corrosion that results from reprocessing is well-known to degrade wire rope drives:

Corrosion accelerates wire-rope deterioration. It reduces rope metallic area, limits flexibility, and leads to uneven wire surfaces that may cause damage to equipment and internal damage to the rope. Corrosion within a wire rope is almost impossible to detect visually, which makes it extremely difficult to determine the true condition of a corroded rope.⁴

41. Plaintiff's reliance on Intuitive's premarket 510(k) notifications to suggest equivalence between traditional endoscopic instruments and EndoWrist instruments⁴² is misplaced. As explained in detail above, the internal drive mechanisms of EndoWrists and traditional instruments are very different. Thus, although they are in many external and functional ways similar to traditional instruments, the cable drive system is significantly different from traditional laparoscopic instruments and does not allow for unlimited, reliable surgical uses.

42. Intuitive designs take these principles into account. To account for potential fatigue and wear failure, the designs are life tested and are limited to a defined number of procedures that are consistent with the reliability demonstrated in these tests. The need for these precautions is clear from the observed life test failures and RMA returned instrument failures.⁴³

43. [REDACTED]

[REDACTED] This is not a meaningful comparison because the cited robotic instruments do not have the same functionality or capabilities as EndoWrist

⁴⁰ Intuitive-00004692 at Intuitive-00004699-700.

⁴ U.S. Navy Wire-Rope Handbook, Vol. 1, pp. 3-15 3-16.

⁴² See, e.g., Compl. ¶ 27.

⁴³ See generally Intuitive-00004692.

⁴⁴ See, e.g., Lamb Rep. ¶ 141.

instruments. Almost all Asensus Senhance instruments do not have wrists;⁴⁵ this robot platform is designed to perform procedures that can be accomplished with conventional laparoscopic instruments, which, as explained above, have much lower dexterity than the da Vinci robot.⁴⁶ The three instruments with wrists listed in the Asensus Senhance catalog have only a single direction of articulation at the wrist (as opposed to the two directions on EndoWrists), and that wrist portion is a single-use disposable.⁴⁷ Asensus does not offer a wristed instrument with unlimited uses.⁴⁸

44. Similarly, Medrobotics' Flex robot instruments do not have wrists.⁴⁹ The instruments are not powered, and all motions of the instrument tips are generated by motions of the surgeon's hands on the instrument control handles.⁵⁰ Because these instruments are constrained to fit through the working channel of a flexible endoscope robot, they do not have rigid shafts, and they have a greatly restricted range of motion compared to EndoWrist

⁴⁵ Senhance Surgical System EMEA Product Catalog, January 2020.

⁴⁶ See [Senhance.com/indications](https://www.senhance.com/indications) (explaining that "The Senhance® Surgical System is intended to assist in the accurate control of laparoscopic instruments . . . in general laparoscopic surgical procedures and laparoscopic gynecological surgery").

⁴⁷ Senhance Surgical System EMEA Product Catalog, January 2020 at 7.

⁴⁸ *Id.*

⁴⁹ See "Expanding the Reach of Surgery," Medrobotics "Flex" brochure, available at: <https://www.easmed.com/main/wp-content/uploads/BROCHURE-Medrobotics-Transanaleasmed.pdf>; see also "Flex Robotic System Technology: How it Works," available at: <https://web.archive.org/web/20200815134035/https://medrobotics.com/gateway/technology/>; "Flexible 'open architecture' instrumentation," available at: <https://web.archive.org/web/20200923215331/https://medrobotics.com/gateway/instruments/>.

⁵⁰ See "Flex Robotic System Technology: How it Works," available at: <https://web.archive.org/web/20200815134035/https://medrobotics.com/gateway/technology/>.

instruments.⁵ Medrobotics does not offer powered or wristed instruments, or instruments with dexterity comparable to the EndoWrist instruments.⁵²

45. In addition to the differences between EndoWrist instruments and traditional laparoscopic instruments highlighted above, EndoWrist instruments require calibration to achieve specified performance. In particular, individual drive cable assemblies are pre-tensioned to specific values in a way that counteracts the anticipated cable-stretch over the life of the instrument.⁵³ Cable tensioning protocols require test fixtures, torque measurement instruments, and accurate execution of a multi-step protocol.⁵⁴ This complicated process is not used for traditional instruments that do not require similar calibration. In this way, I would not expect EndoWrist instruments and traditional instruments to have the same service life.

C. Overview of Interceptor Technology

46. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

⁵ See “Expanding the Reach of Surgery,” Medrobotics brochure, available at: <https://www.easmed.com/main/wp-content/uploads/BROCHURE-Medrobotics-Transanaleasmed.pdf>.

⁵² Furthermore, although Asensus’ and Medrobotics’ Flex robots may not specify a usage limit, their usage and durability in the field is not well understood as they have not yet been on the market nearly as long or as widely adopted as Intuitive’s EndoWrist instruments.

⁵³ See Intuitive-00537574 at Intuitive-00537575.

⁵⁴ See Intuitive-00705141 (Intuitive Manufacturing Process Instructions (MPI) Cable Tensioning, 838012).

[REDACTED] 55 [REDACTED]

[REDACTED] 56

47. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] 2 [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

48. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

60 [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

V. Intuitive's Design Control, Risk Management, and Testing Processes

A. Intuitive's Design Control and Risk Management Processes

50. Intuitive employs rigorous and in-depth design control and risk management processes. Without thorough design control and risk management, surgical robots could be hazardous to both patients and surgical staff. Potential risks for instruments for the da Vinci surgical robot system include: debris falling into the surgical field or patient, increased risk of electrical arcing/burning to patient tissue, unintuitive motion of the da Vinci surgical system,

[REDACTED]

inaccurate or sluggish motions of the EndoWrist instrument, inadequate or restricted ranges of motion, and the EndoWrist instrument failing to be recognized by the da Vinci surgical system.⁶³ Thus, measures to control risk are necessary throughout the product development and manufacturing process. Intuitive has an extensive system in place to evaluate and manage risk. This system is in accord with standard medical device industry practice.⁶⁴

1. Design Control

51. As described by the FDA, design controls “are an interrelated set of practices and procedures that are incorporated into the design and development process,” which result in earlier detection and correction of any “deficiencies in design input requirements, and discrepancies between the proposed designs and requirements.”⁶⁵

52. Intuitive describes its design control process as “[a] systematic framework used to demonstrate that the product works and that it meets the needs of the end-user (intended use) while maintaining safety and effectiveness.”⁶⁶ Design control involves: (i) design verification, which considers and tests the engineering of a product, and (ii) design validation, which considers whether the product meets the needs of the end-user.⁶⁷

53. Within the design control framework, Intuitive’s development process involves detailing what a product must do through a Market Requirements Document (“MRD”) and

⁶³ See generally Intuitive-00538913, Intuitive-00538994.

⁶⁴ See generally Design Control Guidance for Medical Device Manufacturers, US Food and Drug Administration, available at: <https://www.fda.gov/media/116573/download>.

⁶⁵ *Id.* at 1 (“Design controls increase the likelihood that the design transferred to production will translate into a device that is appropriate for its intended use.”). This FDA guidance on design control for medical device manufacturers is applicable to new designs as well as modifications to existing device designs. *Id.* at 2.

⁶⁶ Intuitive-00477325 at Intuitive-00477331.

⁶⁷ Intuitive-00477217 at Intuitive-00477220; see also Intuitive-00477325 at Intuitive-00477331-32.

Product Requirements Documents (“PRD”).⁶⁸ These user and design needs are then implemented through Architectural Requirements Documents (“ARDs”), Functional Requirements Documents (“FRDs”), and lower level functional requirements and specifications.⁶⁹

2. Risk Management

54. Risk management is part of the design process and involves “the systematic application of management policies, procedures, and practices to the tasks of identifying, analyzing, controlling, and monitoring risk.”⁷⁰ As described more fully below and reflected in Figure 6, Intuitive’s risk management processes are integrated into the design control process and continue through the life of a product.⁷

⁶⁸ Intuitive-00477217 at Intuitive-00477222; *see also* Intuitive-00477325 at Intuitive-00477358.

⁶⁹ Intuitive-00477217 at Intuitive-00477222; *see also* Intuitive-00477325 at Intuitive-00477364.

⁷⁰ Design Control Guidance for Medical Device Manufacturers, US Food and Drug Administration, at 5, available at: <https://www.fda.gov/media/116573/download>.

⁷ Intuitive-00477422 at Intuitive-00477424.



*Figure 6.*⁷²

55. The Intuitive risk management process analyzes “risks in design and process, defines requirements to mitigate them, uses design control to trace them to tests, and analyses *[sic]* residual risk.” The risk analysis incorporates both a top-down and bottom-up approach.⁷³

56. From a top-down perspective, major risk management procedures and the associated documentation include a clinical risk analysis (“CRA”) that is formulated early in the product development process. This procedure aims to define potential problems and mitigations

⁷² Intuitive-00477422 at Intuitive-00477424.

⁷³ Intuitive-00477422 at Intuitive-00477424-25.

to guide product definition. The usability risk analysis (“URA”) is formulated after the product is defined and considers how it might be used and misused.⁷⁴

57. From a bottom-up perspective, Intuitive’s risk management procedures include several failure mode and effects analyses (“FMEA”), including Design FMEA, (“dFMEA”), Process FMEA (“pFMEA”), and Supplier Process FMEA (“spFMEA”). FMEA analysis is performed after the product or its manufacturing process have been designed, and looks at potential failures of components and the overall system.⁷⁵ These procedures and additional risk management documents are coordinated with the product design process and design control documents, including definition of user needs, design inputs and outputs, and formal design reviews.⁷⁶ This process manages overall risk in the marketed products.

58. A dFMEA is the key method for defining specific risks in a medical device design. In Intuitive’s dFMEA process, the device is systematically reviewed to determine the ways it could fail and the effects of a failure.⁷⁷ Each significant failure mode is assigned scores for the likelihood of occurrence, the severity of the consequences of failure, and the ability to detect the failure.⁷⁸ These scores can be combined to provide a measure of the risk priority. Important risks are then mitigated, i.e., changes to the design or the product use are implemented to reduce the risk.⁷⁹

⁷⁴ Intuitive-00477422 at Intuitive-00477425-26.

⁷⁵ Intuitive-00477422 at Intuitive-00477424-27.

⁷⁶ Intuitive-00477217 at Intuitive-00477220-24; *see also generally* Intuitive-00477325.

⁷⁷ *See generally* Intuitive-00477829.

⁷⁸ Intuitive-00477422 at Intuitive-00477457. *See generally* Intuitive-00477829.

⁷⁹ *See* Intuitive-00477422 at Intuitive-00477454-457; Intuitive-00477829 at Intuitive-00477844-45.

3. Design Verification and Validation

59. As previewed above, a key aspect of the design control and risk management process is design verification. FDA regulations require that medical device manufacturers perform design verification to “confirm that the design output meets the design input requirements.”⁸⁰ In other words, the design verification process aims to determine whether the performance specifications (design inputs) are met by the new device (design outputs).⁸ The Intuitive design verification process is designed in accordance with these protocols. The goal of design verification is to objectively show that the device is built correctly from an engineering standpoint.⁸²

60. Design control and risk management also involve design validation. FDA regulations also require that medical device manufacturers “establish and maintain procedures for validating . . . device design,” which “ensure[s] that devices conform to defined user needs and intended uses, and . . . include[s] testing of production units under actual or simulated use conditions.”⁸³ The Intuitive design validation process is designed in accordance with these protocols. The goal of design validation is to objectively show that the device meets user needs.⁸⁴

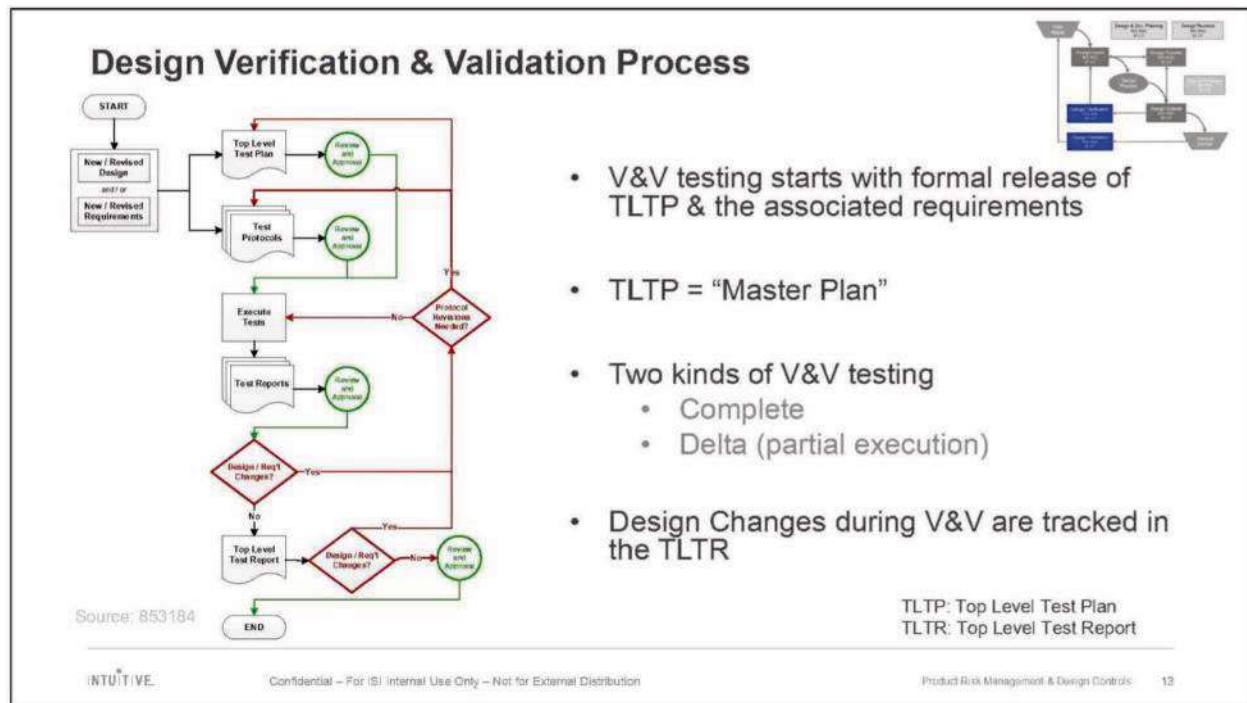
⁸⁰ Design Control Guidance for Medical Device Manufacturers, US Food and Drug Administration, at 29, available at: <https://www.fda.gov/media/116573/download>.

⁸ *Id.* at 29-30.

⁸² *See* Intuitive-00477325 at Intuitive-00477381.

⁸³ Design Control Guidance for Medical Device Manufacturers, US Food and Drug Administration, at 33, available at: <https://www.fda.gov/media/116573/download>.

⁸⁴ *See* Intuitive-00477325 at Intuitive-00477381-82.

Figure 7.⁸⁵

61. Intuitive has a formal design verification and validation process. *See* Figure 7. Verification and validation testing of a new design or a design change begins with a Top Level Test Plan (“TLTP”) that describes the kinds of tests that are to be conducted and the analyses to be performed on the test data, as well as the justification for these tests that relates the specifications to the testing regimen.⁸⁶ Test protocols detail the specific steps of each test and the procedure for documenting the testing process and the results. A Top Level Test Report (“TLTR”) summarizes the overall verification and validation results.⁸⁷ Test reports present the results of the testing as well as analyses and conclusions. Additional documents that specify frequently-conducted test and analysis routines such as standard operating procedures (SOPs)

⁸⁵ Intuitive-00477217 at Intuitive-00477229.

⁸⁶ Intuitive-00477217 at Intuitive-00477229.

⁸⁷ *Id.*

and department operating procedures (DOPs) are used in formulating the test documents, which may be updated as appropriate throughout the verification process.⁸⁸ Testing may range from complete tests against specifications for new device designs to more limited “delta” tests for changes to existing designs.⁸⁹

B. Intuitive Designs and Tests Its EndoWrist Instruments to Reliably and Safely Perform Over a Set Number of “Lives”

62. Intuitive’s EndoWrist instruments are designed and tested to demonstrate the instruments are safe and effective and meet all of their specified requirements and specifications, including their programmed number of instrument uses, otherwise referred to as instrument “lives.”⁹⁰

63. To verify that the design of EndoWrist instruments meets the proposed number of surgical uses, Intuitive conducts life tests.⁹ This process is typically documented by a “Protocol for Reliability/Life Testing” and a “Report for Reliability/Life Testing” or similar documents.⁹² These test procedures typically include initial cleaning and sterilization cycles then alternating simulated surgical procedures, sometimes also referred to as a simulated surgical use (“SSU”), and cleaning and sterilization cycles, which in combination are referred to as Surgical Use Cases (“SUCs”) or life cycles. Attachments to these documents usually include sheets for recording the specific instruments undergoing testing, the equipment used, the observed

⁸⁸ See, e.g., Intuitive-00544199 (referencing, among other documents, Intuitive’s DOP, Product Verification and Validation (Intuitive-00477154); SOP, Statistical Techniques (Intuitive-00477757); and SOP, Risk Management (Intuitive-00477958)).

⁸⁹ Intuitive-00477217 at Intuitive-00477229.

⁹⁰ See generally Intuitive-00477154.

⁹ See, e.g., Intuitive-00544199; Intuitive-00546380; Intuitive-00547846.

⁹² See, e.g., Intuitive-00544199; Intuitive-00544494; Intuitive-00546380; Intuitive-00546343; Intuitive-00547846; Intuitive-00546920.

conditions during tests (e.g., sterilization temperatures), checklists for recording each step and the data that results from the tests.⁹³

64. A representative example of the Intuitive life testing process is captured in the set of documents describing the life test verification of the IS1200 and IS2000/IS3000 Mega SutureCut needle driver (MSCND) and Large SutureCut needle driver (LSCND).⁹⁴ The “Protocol for Reliability/Life Test of MSCND and LSCND Improvements for Grip Cable Life” details the testing process and its justification, as well as the steps required to document the test execution and the results.⁹⁵ This protocol describes the goal of the tests in terms of functional requirements (e.g., reliable operation for ten human uses) and the instrument models to which it applies, and uses a worst-case analysis to determine which specific instrument types are most likely to experience failure and thus should be tested.⁹⁶

65. This protocol also uses a statistical Weibull Design of Reliability analysis to determine the number of instrument samples and use cycles that are required to statistically “prove” a number of instrument lives.⁹⁷ The analysis applied in connection with the Protocol for Reliability/Life Test of MSCND and LSCND Improvements for Grip Cable Life uses a goal of 90% reliability and 90% confidence (“90/90”) for ten human uses.

66. This Protocol for Reliability/Life Test of MSCND and LSCND Improvements for Grip Cable Life is a test following a design change for “updating the proximal clevis pin”

⁹³ See, e.g., Intuitive-00544199 (describing attachments and checklists).

⁹⁴ See generally Intuitive-00544186; Intuitive-00544195; Intuitive-00544197; Intuitive-00544198; Intuitive-00544199; Intuitive-00544388.

⁹⁵ See generally Intuitive-00544199.

⁹⁶ *Id.* at Intuitive-00544200.

⁹⁷ *Id.* Weibull Design of Reliability analysis is further detailed in the Intuitive’s “Statistical Techniques Department Operating Procedure,” Intuitive-00477757.

that was instituted to “reduce the occurrence of grip cable failures.”⁹⁸ The tests are designed to confirm that this change to the design maintains the specified level of reliability and confidence, so a relatively small sample size of eight units was tested due to the presence of a similar predicate device.⁹⁹ Each of these units is put through a total of 15 “life cycles,” which comprise an initial six cleaning and sterilization cycles, followed by fifteen simulated surgical uses and cleaning and sterilization cycles to validate 10 human surgical uses.⁰⁰

67. Simulated surgical procedures for life tests are described in the test report as “developed by the Clinical Development Engineering team.” *See* Figure 8. The simulated surgical procedure requires a series of maneuvers of the instrument that replicate how the instrument is used in an applicable laparoscopic surgical operation. *See* Figures 8, 9, 10. In the example of the life testing of the MSCND and LSCND instruments, these steps include wrist circles (moving the instrument tip in a circular pattern), needle throws (driving the needle through a single stitch), suture pulls, tissue lifts, and tissue pushes. *See* Figure 9. Animal tissue models (in this case a beef rib roast) or synthetic models are used to provide reaction forces that emulate the forces produced in surgical procedures. *See* Figure 11. For example, the tissue push maneuver is described as “[p]ush with a force of approximately 2 lbs”⁰ Maneuvers are done in an order that replicates typical surgical usage and repeated a specific number of times that conservatively approximates repetitions in surgery.⁰²

⁹⁸ Intuitive-00544199 at Intuitive-00544201.

⁹⁹ Intuitive-00544494 at Intuitive-00544494.

⁰⁰ Intuitive-00544199 at Intuitive-00544200, Intuitive-00544209.

⁰ *Id.* at Intuitive-00544201.

⁰² *See* Intuitive-00544494 at Intuitive-00544496.

68. By defining a simulated surgical procedure based on observed maneuvers used in applicable laparoscopic surgeries, using animal tissue or synthetic models to emulate forces used in surgical procedures, performing maneuvers in an order replicating typical surgical usage and employing a conservative approximation of the number of maneuvers to be performed during an applicable laparoscopic surgical operation, Intuitive tests instruments in a way that helps ensure the instruments operate reliably and safely over their programmed number of instrument uses.

8. Definitions

- A) **Simulated Surgical Procedure** – A “Simulated Surgical Procedure” for the instrument was developed by the Clinical Development Engineering team. It is comprised of surgical tasks that are defined to represent actual maneuvers performed during minimally invasive surgical operations. The number of repetitions to be completed was determined by conservatively estimated the number of such maneuvers performed during an applicable laparoscopic surgical operation. Attachment 5 (Protocol 862287-01P) provides further details.

*Figure 8.*⁰³

⁰³ Intuitive-00544494 at Intuitive-00544496.

7 Definitions

The following definitions are to describe the specific surgical maneuvers as outlined in section 12.0.

A)

B)

C)

D)

E)

F)

G)

H)



*Figure 9.*¹⁰⁴

¹⁰⁴ Intuitive-00544199 at Intuitive-00544201.

12 Simulated Surgical Procedure (SSP)

The following table defines a clinical life simulation cycle for the MSCND instrument. This cycle utilizes the motions defined above (see section 7) and arranges/distributes them in a way that more closely approximates the expected usage patterns.

MSCND, One (1) Simulated Life Use

# of executions	Task

Figure 10.¹⁰⁵

¹⁰⁵ Intuitive-00544199 at Intuitive-00544206.

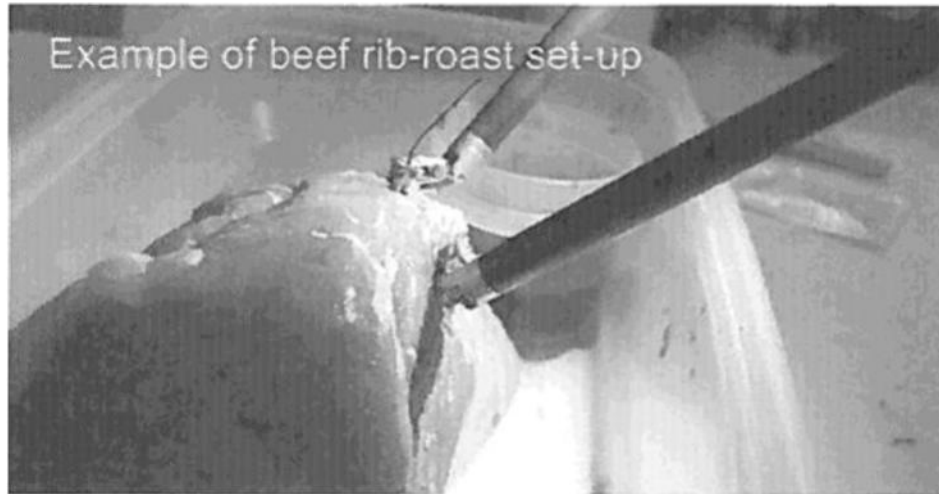


Figure 11.⁰⁶

69. As expected with a rigorous life testing process, failures are observed during life testing of Intuitive EndoWrist instruments. In the MSCND and LSCND example, one of the eight instruments under test suffered a failure on the fourth test cycle, when “the grip close cable derailed from the distal idler pulley during testing.”⁰⁷ Other examples of life testing that resulted in failures includes:

- Life testing of the 8mm permanent cautery hook, where failures were observed in three of the twelve test instruments during SUC trials 12, 17 and 21.⁰⁸
- Life testing of 8mm monopolar curved scissors, where a derailment failure occurred in SUC trial 6.⁰⁹

⁰⁶ Intuitive-00544456 at Intuitive-00544464.

⁰⁷ Intuitive-00544494 at Intuitive-00544500; *see also id.* at Intuitive-00544497.

⁰⁸ Intuitive-00589150 at Intuitive-00589153.

⁰⁹ Intuitive-00546920 at Intuitive-00546920. Instrument intuitive motion also failed for a different instrument in SUC trial 11 and for two additional instruments in SUC trial 12. *See id.*

- Life testing of 8mm monopolar curved scissors where a cable break was observed during SUC trial 7.⁰ (Note that Intuitive considers the IS2000/3000 and IS4000 Monopolar Curved Scissors to be equivalent in terms of their distal portions.)

70. As mentioned above, Intuitive has standard procedures for modeling the reliability of the instrument by fitting the life test data to a Weibull reliability model.² The Weibull Distribution is “a parameterized continuous probability distribution that is commonly used in failure analysis.”³ Use of the Weibull model provides the ability to predict the reliability of the instrument as a function of number of uses, as well as uncertainty estimates (confidence intervals) for these estimates.⁴ This model is also used to establish testing parameters such as sample size.⁵ The use of these procedures is important because it accounts for the potential for failures throughout a product’s useful life and ensures instruments meet minimum reliability requirements throughout that useful life.⁶ The Weibull model is a well-recognized and appropriate method for modeling the reliability of instruments.

C. As EndoWrist Instruments Are Used in a Hospital Setting to Perform Surgical Procedures, They Experience Wear and Tear that Ultimately Leads to Instrument Failure.

71. Gradual degradation of an instrument over time is expected given the design of EndoWrist instruments and it is one of the risks that is identified through Intuitive’s risk analyses

⁰ Intuitive-00546343 at Intuitive-00546360.

See e.g., Intuitive-00546343. The IS4000 system is commercially known as the da Vinci Xi surgical system.

² *See* Intuitive-00477597.

³ *Id.*

⁴ *See* Intuitive-00477597; Intuitive-00477620.

⁵ *See* Intuitive-00477620.

⁶ Intuitive-00477597 at Intuitive-00477597-98.

and life testing and is factored into EndoWrist usage limits. In addition to identified failure modes/gradual degradation inherent in normal usage, instruments are exposed to stresses by surgeons and hospital staff in the ordinary course of their use. Intuitive observes and tracks these failures in instruments that have been sold to customers and used on patients through its return material authorization (RMA) process. The RMA process allows for customers to return EndoWrist instruments that experience failure during their intended lives for a prorated discount.

72. As Intuitive notes, “RMA data is an indicator of instrument reliability because it is correlated to the number of reported instruments that do not meet performance requirements throughout their intended life. Although Intuitive performs life testing to quantify how many lives an instrument can be qualified for, there is some possibility that the assumptions made in the life testing methodology is not representative of real-world use. Although life testing is a validated process for qualifying instrument lives, Intuitive also confirms life testing data with RMA data trends, which originate from real-world use, rather than simulated surgical use, which follows methods generated within Intuitive. If RMA rates were to be misaligned with expected reliability predicted from life testing, then life testing would need to be modified to align with the reality observed through RMA rates. Neither RMA rates nor life testing is solely responsible for validating the safety of the extension of lives.”⁷

73. Instruments are returned to Intuitive through the RMA process due to observed or alleged problems or failure during warranty. Intuitive has identified a variety of instrument failures within their established usage limits through the RMA process, including:

- Cable breakages⁸;

⁷ Intuitive-00004692 at Intuitive-0000470-01.

⁸ See e.g., Intuitive-00695006 (RMA data) at Tab 1 Row 37.

- Cable fraying ⁹;
- Cable derailment ²⁰;
- Cable slack ² ;
- Abuse in cleaning ²²;
- Decreased electrical insulation in both cautery and non-cautery EndoWrist instruments ²³; and
- Electrode tips becoming pitted and discolored, ²⁴ among others.

74. These failures have been observed during the warranty period, which covers only the number of lives validated by Intuitive. This RMA data provides further evidence that EndoWrist instruments can and do fail at times, even within the number of lives set for their use. Further, because Intuitive observes through its RMA process many instrument failures that occur as a result of wear and tear, I would expect Restore's and Rebotix's attempts to increase instrument usage limits above the limits prescribed by Intuitive will only increase failure rates. Intuitive's EndoWrist instruments have been used in millions of procedures, and Intuitive thus has a large amount of data from real-world use. ²⁵ By contrast, there is minimal real-world use data from remanufactured instruments.

⁹ See e.g., *id.* at Tab 1 Row 54.

²⁰ See e.g., *id.* at Tab 1 Row 697.

² See e.g., *id.* at Tab 1 Row 5284.

²² See e.g., *id.* at Tab 1 Row 121.

²³ See e.g., *id.* at Tab 1 Row 856, Row 3365.

²⁴ See e.g., *id.* at Tab 1 Row 91783.

²⁵ For example, Intuitive's systems were used for over 1.5 million procedures in 2021 alone. Intuitive Surgical, Inc., Annual Report 2021, <https://isrg.intuitive.com/static-files/704322bf-cb0d-4ed1-954c-8eb46a070f70>.

75. Via the RMA process, Intuitive also observes failures in instruments that have had their useful lives extended by third parties such as Restore and Rebotix, which were returned to Intuitive. Such failures include:

- Failure of instrument to be recognized by da Vinci surgical robot ²⁶;
- Abuse in cleaning ²⁷;
- Broken or dislodged wires ²⁸; and
- Damaged instrument components ²⁹.

76. In addition, I have reviewed evidence produced by Restore of complaints it received from customers relating to failure of instruments which had usage limits extended, including:

- [REDACTED]
- [REDACTED]
- [REDACTED].

77. [REDACTED]

[REDACTED]

[REDACTED] ■ [REDACTED]

²⁶ See *id.* at Tab 2 Rows 15, 17, 44 and 47.

²⁷ See *id.* at Tab 2 Row 24.

²⁸ See *id.* at Tab 2 Row 28-31.

²⁹ See *id.* at Tab 2 Rows 18, 28-31.

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

[REDACTED]

[REDACTED]

VI. Limitations and Risks of the Interceptor and “EndoWrist Service Procedure”

78. The Rebotix Interceptor and the “Endo Wrist Service Procedure” developed by Rebotix are purported to extend the reliable life of certain EndoWrist instruments to at least nine surgical uses beyond their usage limit.³⁵ However, significant problems exist with Rebotix’s approach such that in my opinion, Rebotix cannot *reliably or safely* extend the lives of EndoWrist instruments to an additional nine lives beyond their initial usage limit. In my opinion, Rebotix’s service procedure and its risk management and life testing methods are flawed, making Rebotix’s claim that it can reliably extend the lives of EndoWrist instruments unreliable and unsupportable.

79. [REDACTED]

[REDACTED]

[REDACTED].³⁶ Since Rebotix’s safety and reliability claims were

unreliable and unsupportable, both Restore's and SIS's safety and reliability claims are therefore similarly unreliable and unsupportable.

A. Risks Associated with the Rebotix "EndoWrist Service Procedure"

80.

[REDACTED]

81.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

Relationship Duration	Percentage of Respondents
Less than 1 year	~10%
1 to 2 years	~45%
2 to 3 years	~15%
3 to 4 years	~95%
4 to 5 years	~85%
5 to 6 years	~40%
6 to 7 years	~15%
7 to 8 years	~10%
8 to 9 years	~10%

[REDACTED]

89. Intuitive engineering documents describe this type of particulate contamination as a serious potential risk. For example, the 8mm instrument FMEA indicates that potential failures for various components within the proximal housing could result in “[p]arts or fragments fall[ing] into patient”; Intuitive assigns this risk a severity score of 9 out of 10 and requires mitigation by life testing.⁵⁹

90. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

e.g., debris falling into a patient could occur without the surgeon noticing them and without the device itself becoming unusable. The presence of manmade materials within the body can trigger the well-known foreign body reaction, which is an inflammatory process that can lead to pain, adhesions, infections, and disruptions of normal physiological function.⁶ Even microscopic debris (e.g., filaments from a broken cable) can lead to serious adverse responses in patients following surgery.⁶²

⁵⁹ See Intuitive-00538994 at Tabs 1, 2, and 11.

[REDACTED]

⁶ Anderson, James M., Analiz Rodriguez, and David T. Chang. “Foreign body reaction to biomaterials,” in *Seminars in Immunology*, vol. 20, no. 2, pp. 86-100, 2008; Wang, Cecily F., James Cipolla, Mark J. Seamon, David E. Lindsey, and S. Peter Stawicki. “Gastrointestinal complications related to retained surgical foreign bodies (RSFB): A concise review,” in *OPUS* 12: 11-8, 2007.

⁶² Truscott, Wava. “Impact of Microscopic Foreign Debris on Post-Surgical Complications,” in *Surgical Technol. Int’l*, vol. 12:34-46, 2004.

91. [REDACTED]

92. [REDACTED]

[REDACTED] While Intuitive uses specific tools (e.g., a tensioning tool and 40 in-oz torque driver as well as test fixtures for the instrument) to pre-tension cables to specific values to counteract the anticipated cable-stretch over the life of the instrument,¹⁶⁴ [REDACTED]

¹⁶⁴ See *supra* ¶ 45 (citing Intuitive-00537574 at Intuitive-00537575 and Intuitive-00705141 (Intuitive Manufacturing Process Instructions (MPI) Cable Tensioning, 838012); see also Nov. 8, 2022 Grant Duque (30(b)(1)) Tr. at 136:20–146:13.

[REDACTED]

93. This difference between Intuitive and Rebotix protocols has potential consequences to instrument reliability and patient safety. [REDACTED]

[REDACTED]

94. [REDACTED]

[REDACTED]

[REDACTED]

⁶⁸ See, e.g., Intuitive-00538913 at “2) IMA Backend Assy Processes” Rows 40, 41; Intuitive-00544494 at Intuitive-00544497. [REDACTED]

⁶⁹ See, e.g., Intuitive-00537574 at Intuitive-00537575 (“When each instrument is manufactured, the axis cables are tensioned to specific values. The tension ensures that the instrument remains functional throughout its lifetime as cable stretch occurs.”).

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] RMA results show failure modes that should be checked, including frayed cables within the proximal housing ⁷² and corrosion or contamination of the instrument bearings. ⁷³ Finally, as noted above in section IV.B, [REDACTED]

[REDACTED]

95. In addition to the issues detailed above, there are numerous other problematic aspects of Rebotix's servicing procedure. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

⁷² See, e.g., Intuitive-695006 (RMA data) Tab 1 at Row 16798, 40346.

⁷³ See, e.g., Intuitive-695006 (RMA data) Tab 1 at Row 173, 579.

⁷⁴ U.S. Navy Wire-Rope Handbook, Vol. 1, p. 3-15 (explaining that "[c]orrosion within a wire rope is almost impossible to detect visually, which makes it extremely difficult to determine the true condition of a corroded rope.").

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

B. Rebotix's Inadequate Risk Management and Life Testing

1. Rebotix's Risk Management

96. [REDACTED]

[REDACTED] There are, however, a number of deficiencies in these procedures. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

97. In support of my analysis of Rebotix's risk management practices, I reviewed the documentation identified by Rebotix as [REDACTED]

[REDACTED] contrast, Intuitive's reprocessing instructions refer specifically to "clean, dry air" when air is used to dry EndoWrist instruments after sterilization. *See, e.g.,* da Vinci S and Si Instrument Reprocessing Instructions for Automated Cleaning and Disinfection, at 36, https://manuals.intuitivesurgical.com/c/document_library/get_file?uuid=d237e175-3fce-3844-863e-37e733afe0d6&groupId=73750789; da Vinci Xi Instrument Reprocessing Instructions for Automated Cleaning and Disinfection, at 36, https://manuals.intuitivesurgical.com/c/document_library/get_file?uuid=b1b9f169-4503-9ea9-6db9-9243c28d5221&groupId=73750789. "Clean air" is a widely used term that refers to a specific quality of air that is higher than "shop air."

⁷⁸ *See e.g.,* Intuitive-00538994 (8mm Instrument Family FMEA with various tabs devoted to potential mechanical failures).

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

98. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] As noted above, during normal use of an EndoWrist instrument, drive cables may be damaged, bearings may be contaminated, and other faults may arise that are not visible under inspection. *See supra* § V.C.

102. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

103. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

104.

[REDACTED]

[REDACTED]

105.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] The FDA website provides a description of
MAUDE: “Manufacturer and User Facility Device Experience (MAUDE) database represents

108. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

110. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

reports of adverse events involving medical devices. The searchable database contains the last 10 years of medical device report (MDR) data. MAUDE may not include reports made according to exemptions, variances, or alternative reporting requirements granted under 21 CFR 803.19. The downloadable data files consist of voluntary reports since June 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August 1996. The public may search the database for information on medical devices that may have malfunctioned or caused a death or serious injury. Data for the past 10 years is available through the end of the previous month.” U.S. Food and Drug Admin., Manufacturer and user facility device experience database (Maude), <https://www.fda.gov/medical-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities/manufacture-and-user-facility-device-experience-database-maude> (last visited Jan. 18, 2023).

⁹⁸ REBOTIX090153. MDR refers to FDA Medical Device Reporting, *see* <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

[REDACTED]

[REDACTED]

[REDACTED]

111.

[REDACTED]

112.

[REDACTED]

2. Rebotix's Life Testing

113.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] However, as with Rebotix’s risk management procedures, there are numerous deficiencies in Rebotix’s life testing.

114. [REDACTED]

[REDACTED]

[REDACTED]

115. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

116. [REDACTED]

[REDACTED] Intuitive’s life test verification of EndoWrist instruments involves subjecting instruments to forces similar to those encountered during surgery that can and do limit instrument life.²⁰⁹ For example, as discussed in Section V.B above, Intuitive’s delta life test verification of the IS1200 and IS2000/IS3000 Mega SutureCut needle driver (MSCND) and Large SutureCut needle driver (LSCND) used animal tissue models to provide reaction forces (e.g., forces of approximately 2 lbs) simulating those forces produced in surgical procedures.²⁰ In the case of the MSCND and LSCND instruments, one of the eight instruments tested failed on

[REDACTED]

²⁰⁹ See generally Intuitive-00544199; Intuitive-00544494.

²⁰ Intuitive-00544199 at Intuitive-00544201.

the fourth test cycle due to a cable derailment.² Moreover, Intuitive's worst-case analysis for its instruments includes and accounts for mechanical forces, for example, Intuitive selects the instruments that have the highest design loads (defined as the "comparative ranking of the stress an instruments drivetrain components are subject to during use") or the highest levels of cable tension as worst-case instruments.^{2 2}

117. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Intuitive

life testing, where large forces are required to be applied to the instruments to simulate both tissue interactions and collisions or other interactions between instruments.^{2 5} [REDACTED]

[REDACTED]

[REDACTED]

118. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

² Intuitive-00544494 at Intuitive-00544497.

^{2 2} Intuitive-00027876 at Intuitive-00027879-00027881.

[REDACTED]

[REDACTED].

^{2 5} Intuitive-00544199 at Intuitive-00544201 (noting that "2 lbs" of force applied in the MSCND and LSCND tests).

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

119. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

^{2 6} See *supra* ¶ 70 (citing Intuitive-00477597; Intuitive-00477620).

[REDACTED]

[REDACTED]

[REDACTED]

120. [REDACTED]

[REDACTED] The Extended Use Program aimed to take advantage of diverse improvements in instrument design and reprocessing practices relevant to the X and Xi instruments to enable customers to use certain X and Xi instruments for more than the originally validated ten lives. The “White Paper, Extended Lives Supporting Materials” document provides details on the program and the life testing that provided the basis for life extension:

Da Vinci instruments, which are used in procedures and are reprocessed between uses, experience degradation throughout their lifetime. Instrument degradation can eventually lead to poor instrument performance or a device failure. To ensure reliability and reduce the possibility of instrument failures occurring during a procedure, the number of uses per instrument are limited. Fewer instrument lives increases confidence of adequate performance, but also results in additional customer cost by requiring more frequent replacement and purchasing. Based on a number of design and manufacturing improvements made over the past several years, as well as efforts to reduce reprocessing practices at hospitals, and in an effort to reduce costs for the customer, a number of X/Xi instruments have been re-evaluated for extended life reliability. The results of this testing have made it possible to increase certain instruments’ rated use and reprocessing life, while still ensuring safe and adequate performance throughout the instrument lifetime, with no impacts to our risk-based confidence and reliability requirements....

To analyze the ability of instrument lives to be extended safely, life testing was performed on X/Xi instruments and a cumulative risk analysis was completed and summarized. Life testing that was used previously to validate the specification of 10 lives (for most instruments) was completed “to failure” to determine the maximum allowable number of lives for each instrument, utilizing knowledge gained from years of instrument usage. Although each design change had its own risk analysis, a cumulative risk analysis was

completed to understand how risk is affected by all of the changes combined.²²⁰

121. While the Extended Use Program was limited to certain da Vinci model X/Xi instruments, and found that certain X/Xi instruments are able to be used safely and reliably for a few more than ten uses, Intuitive's testing showed that none of the X/Xi instruments could reliably and safely be used for the number of times third parties claim they can safely reset S/Si instruments.²² I would expect these findings to apply with equal or greater force to S/Si instruments. Intuitive made improvements to the X/Xi instruments over time such that certain of the X/Xi instruments may have a small number of reliable uses above 10, as Intuitive demonstrated as part of the Extended Lives Program. For example, Intuitive changed a number of components used in X/Xi instruments including the pitch cable, grip cable, and the grips.²²² Since those component changes were not made to S/Si instruments, there is no basis to assume that those instruments would perform reliably over more than 10 uses.

122. In Intuitive's Extended Use Program testing, twelve different X/Xi instrument models and a total of 250 instruments were tested. Life test protocols involving an initial reprocessing cycle, followed by interleaved surgical use cycles (SUCs) and reprocessing cycles, consistent with Intuitive's typical life testing protocols described above.²²³ The instruments were put through 14 to 22 SUCs, and at least one instrument of every model suffered failures by SUC

²²⁰ Intuitive-00004692 at Intuitive-00004692.

²² Intuitive-00290857 at Intuitive-00290859; Oct. 27, 2022 Nickola Goodson Tr. at 222:13 20, 232:18 233:18, 233:19 24; Oct. 6, 2022 Disha Peswani Tr. at 106:8 17, 113:21 114:4, 114:9 18, 115:4 12, 156:2 9; Intuitive-00004692; Intuitive-00004685; Intuitive-00552529; Intuitive-00552530; Intuitive-00552535.

²²² Oct. 6, 2022 Disha Peswani Tr. at 116:2 13.

²²³ See *supra* §§ V.A-B.

22. Further, a total of 70 failures were observed from the 250 units. 52 of those instruments failed as a result of cable drivetrain stretch/fatigue/yield.²²⁴

123. Using Weibull analysis, Intuitive engineers showed that the extended life test results provided evidence that the instruments were reliable for between 12 and 18 uses. None of them were shown to meet reliability standards for the number of uses (19 or 29) that Rebotix claims to have verified.²²⁵

[REDACTED]

C. Rebotix's [REDACTED]
[REDACTED] Do Not Support Any Safety and Reliability Claims.

125. [REDACTED]

[REDACTED] ”227 [REDACTED]

[REDACTED] ”228 [REDACTED]

[REDACTED] [REDACTED]

²²⁴ Intuitive-00552535.

²²⁵ *See id.*; *see also e.g.*, Rebotix's Responses and Objections to Intuitive's Second Set of Interrogatories, at Interrogatory 3. I note that the spreadsheet summarizing Intuitive's extended life test results indicates that the ProGrasp instrument "Rated USE life Qualified" is 20 uses. *See* Intuitive-00552535. However, the original test document (862214-04R) and the Extended Lives White Paper both state that the verified number of uses is 18. *See* Intuitive-00551503; Intuitive-00004692.

[REDACTED]

[REDACTED]

[REDACTED]

126. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] 230

127. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].

[REDACTED]

[REDACTED]

129. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

130. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

131. It is not possible to determine from the summary information provided what was included in the testing and evaluation. [REDACTED]

[REDACTED]

[REDACTED].

132. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] The document does not state which set of instrument models were selected. Without such information, it is not possible to determine if the selection process was appropriate and effective.

[REDACTED]

[REDACTED]

[REDACTED]

133. [REDACTED]

Here again, the document does not provide essential information to determine safety and reliability. [REDACTED]

134. [REDACTED]

VII. Intuitive's Efforts to Create a Refurbishment Program Do Not Prove the Safety or Reliability of EndoWrists Reset by Third Parties.

135. I understand that between 2016 and 2020, Intuitive considered starting an EndoWrist refurbishment program for X and Xi instruments.²⁴⁰ Plaintiff's experts appear to assume Intuitive's consideration of such a refurbishment program constitutes evidence that third-party EndoWrist "reset" offerings are safe and reliable.²⁴ I disagree.

²⁴⁰ Oct. 27, 2022 Goodson Tr. at 70:11 72:20.

²⁴ See Lamb Rep. ¶¶ 60 63, 137 39; Bero Rep. § VII.

136. Intuitive ultimately did not implement a refurbishment program because it would have needed to demonstrate the reliability of the refurbished instruments and it determined that the cost associated with part replacements necessary to achieve that reliability became “cost prohibitive.”²⁴² For example, Intuitive replaced the EndoWrist cables during its refurbished instrument testing process but still observed broken cables during life testing.²⁴³ In other words, Intuitive concluded that safely and reliably refurbishing EndoWrist instruments required replacing components of the instruments, not simply sharpening them and manually adjusting cables.

137. The outcome of Intuitive’s refurbishment project testing therefore actually supports my conclusion that the Rebotix process was inadequate, rather than suggesting that the third-party EndoWrist reset processes are safe and reliable.

VIII.

138.

²⁴⁴

²⁴⁵

139.

²⁴⁶

²⁴² *Id.* at 73:6 13.

²⁴³ *See, e.g.*, Intuitive-00626429 at Intuitive-00626431 32.

[REDACTED] 247 [REDACTED]

[REDACTED] 248

140. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] 249 [REDACTED]

[REDACTED] 250

B. The Rebotix Process and [REDACTED]s Are Materially Different.

141. It is my opinion that there are significant differences between the Rebotix Process for remanufacturing S/Si EndoWrist instruments and the [REDACTED]

[REDACTED]

[REDACTED] Some examples are listed below.

142. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

143.

[REDACTED]

[REDACTED]

[REDACTED],²⁵

[REDACTED]

[REDACTED]²⁵²

144.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

(6)

[REDACTED]

[REDACTED]²⁵⁴,

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].

(7) [REDACTED] 255,

(8) [REDACTED]

[REDACTED] 256, [REDACTED]

(9) [REDACTED]

[REDACTED] 257

146. [REDACTED]

[REDACTED] 258

147. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

148. [REDACTED]

[REDACTED] [REDACTED]

[REDACTED] As explained in Section IV.B above, “The corrosion that results from reprocessing is well-known to degrade wire rope drives.” Corrosion accelerates wire-rope deterioration by reducing rope metallic area, limiting flexibility, and creating uneven wire surfaces that may cause internal damage to the rope and other equipment.²⁶⁴ While not all corrosion is externally visible in these instruments, inspection can detect external signs of degradation and serves to enhance instrument safety. [REDACTED]

[REDACTED]

149. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

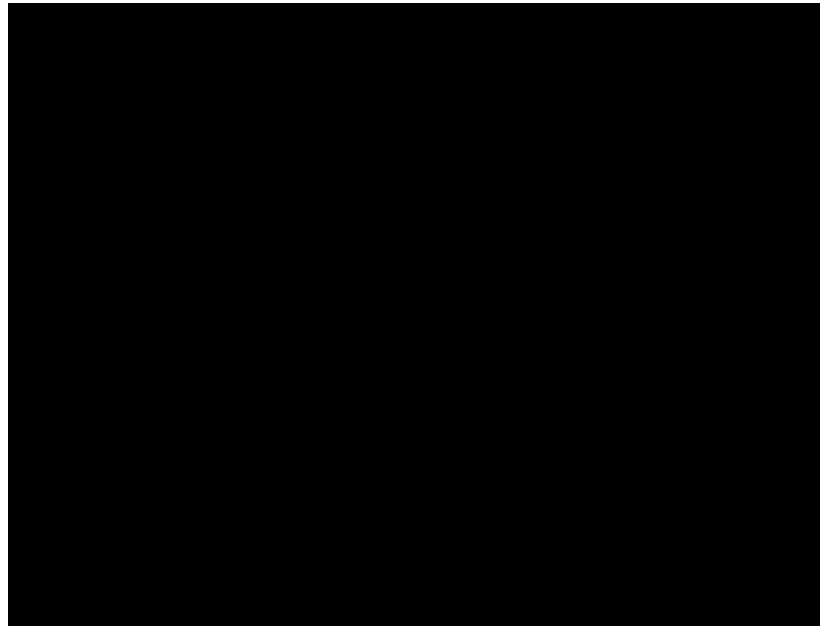
[REDACTED]

²⁶³ [REDACTED]

²⁶⁴ *Id.* (quoting U.S. Navy Wire-Rope Handbook, Vol. 1, p. 3-15).

[REDACTED]

[REDACTED]



[REDACTED]

150.

[REDACTED]

[REDACTED]

[REDACTED] ”268 [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] [REDACTED]

[REDACTED] [REDACTED]

C. The Rebotix Process and [REDACTED] are Supported by Materially Different Risk Management and Life Testing Data.

151. It is my opinion that there are significant differences between the risk management and life testing data Rebotix had access to in connection with the Rebotix Process

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

and [REDACTED] Some examples are listed below.

152. [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]

- [REDACTED]
[REDACTED]
- [REDACTED]
[REDACTED]
- [REDACTED]
[REDACTED]²⁷

[REDACTED]
[REDACTED]
[REDACTED]²⁷²

153. [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]²⁷³

[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]

[REDACTED] 274

154. [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]

[REDACTED] 279

155.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] 280 [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] 28

156. Such testing provides quantitative information for assessing the reliability of the remanufactured instruments, which is absent from the limited information available in connection with the Rebotix Process.

[REDACTED]
[REDACTED]
[REDACTED]

D. Significantly Greater Safety Risks Are Created by Resetting an EndoWrist Usage Counter Multiple Times.

157. [REDACTED]

[REDACTED] I am not aware of any support for that claim. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]²⁸⁴ [REDACTED]

[REDACTED]

[REDACTED]²⁸⁵

[REDACTED]

[REDACTED]

[REDACTED]

see also Restore-00087134.

²⁸⁵ Restore-00089490 at Restore-00089492 93 [REDACTED]

159. [REDACTED]

[REDACTED]

[REDACTED]

160. As explained above, data and analyses show that mechanical failures represent a large portion of all failures observed in EndoWrist instruments, and that continued use of EndoWrists beyond their originally specified number of uses increases the risk of instrument failure.²⁸⁶

161. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

162. The above evidence shows that EndoWrist instrument failure rates increase with the number of procedures where they are used. This implies that the reliability of these instruments will continue to decrease as they are remanufactured for use beyond 20 lives.

I declare under penalty of perjury that the foregoing is true and correct. Executed this 18th day of January, 2023, at Brewster, Massachusetts.

A handwritten signature in black ink, appearing to read "Robert D. Howe", is written over a horizontal line.

Robert D. Howe, Ph.D.
January 18, 2023

Appendix A

Robert D. Howe

Harvard University
Paulson School of Engineering and Applied Sciences
4.218 Science and Engineering Complex
150 Western Ave., Boston, MA 02134 USA

office phone: +1 (617) 496-8359
mobile phone: +1 (617) 877-0930
howe@seas.harvard.edu
<http://biorobotics.harvard.edu>

Employment

- 1997-present **Abbott and James Lawrence Professor of Engineering**, Harvard Paulson School of Engineering and Applied Sciences. Conducting research in robotic manipulation, tactile sensing, surgical robotics, medical image processing, human-machine interfaces, and biomechanics; teaching graduate and undergraduate engineering courses.
- 1994-1997 **Associate Professor of Mechanical Engineering**, Harvard University
- 1990-1994 **Assistant Professor of Mechanical Engineering**, Harvard University
- 1984-1990 **Research Assistant**, Mechanical Engineering Department, Stanford University
- 1981-1983 **Research Physicist**, High Temperature Gasdynamics Laboratory, Stanford University. Developed optical and electronic research instruments, conducted flow visualization and combustion diagnostics experiments.
- 1979-1981 **Electronics Engineer**, Kratos Display Systems, Los Gatos, CA. Designed analog and digital electronics.

Secondary Academic Appointments

- Founding Co-Director, Harvard MS/MBA Program (Dual Master's degree program between Harvard's Business and Engineering Schools), 2018-present
- Area Dean for Bioengineering (equivalent to department chair), Harvard Paulson School of Engineering and Applied Sciences, 2010-2011, 2012-2016
- Associate Dean for Academic Programs (Chief Academic Officer), Harvard School of Engineering and Applied Sciences, 2008-2011
- Adjunct Professor, Department of Biomedical Engineering, Tufts University, 2007 - present
- Member of the Core Faculty, Harvard-MIT Division of Health Sciences and Technology, 1999 - present

Thinker in Residence, Deakin University, Australia, Fall 2015

Visiting Professor, Singapore University of Technology and Design, Spring 2012

Visiting Scientist, INRIA Sophia-Antipolis, France, Spring 2004

Visiting Scholar, Mechanical Engineering Department, Stanford University, Spring 1999

Visiting Scientist, Artificial Intelligence Laboratory, Massachusetts Institute of Technology, Fall 1998

Education

- 1990 Doctor of Philosophy in Mechanical Engineering, Stanford University.
- 1985 Master of Science in Mechanical Engineering, Stanford University.
- 1979 Bachelor of Arts in Physics, Reed College.

Selected Professional Awards and Honors

Fellow, Institute of Electrical and Electronics Engineers (IEEE), 2012.
 Fellow, American Institute for Medical and Biological Engineering (AIMBE), 2007.
 I.S. Ravdin Lecture, American College of Surgeons 97th Annual Clinical Congress, San Francisco, 2011.
 Keynote address, 5th International Conference on Functional Imaging and Modeling of the Heart, Nice, France, 2009.
 Keynote address, SPIE Medical Imaging Conference, San Diego, 2008.
 Keynote address, EuroHaptics Conference, Munich, 2004.
 Whitaker Foundation Biomedical Engineering Research Grant (Career development award), 1995.
 National Science Foundation Young Investigator Award, 1993.

Selected Professional Service

Journals

Associate Editor, *International Journal of Robotics Research*, 2019-present
 Advisory Board, *Science Robotics*, 2017-present.
 Editorial Board, *Medical Image Analysis*, 2008-present.
 Management Committee, Founding member, *IEEE Transactions on Haptics*, 2007-2013.
 Associate editor, *IEEE Transactions on Robotics and Automation*, 1994-1998.

Conferences and workshops

Co-organizer, Workshop on Closing the Loop on Upper-Limb Assistive Device Design, Sensing, Control, & Clinical Practice, IEEE RAS/EMBS International Conference on Biomedical Robotics & Biomechatronics (BioRob), August 21, 2022, Seoul.
 Co-organizer, Tutorial on Jamming in Robotics: From Fundamental Building Blocks to Robotic Applications, IEEE International Conference on Robotics and Automation (ICRA), May 23, 2022, Philadelphia.
 Program Co-Chair, International Conference on Medical Image Computing and Computer-Assisted Intervention (MICCAI), 2014; Program Committee, 1998, 2000, 2002-2007, 2016, 2017.
 Program Committee, Intl. Symposium on Medical Robotics and Computer Assisted Surgery, 1994, 1995, 1997.
 Program Committee, Intl. Conference on Functional Imaging and Modeling of the Heart, 2009, 2011, 2013.
 Area Chair, Robotics: Science and Systems Conference (RSS), Philadelphia, August 16th-19th, 2006 and Cambridge, July 12-16, 2017; program committee member 2007, 2018.
 Co-Chair, International Program Committee, First IEEE World Haptics Conference (First Joint Eurohaptics Conference and Symposium on Haptic Interfaces for Virtual Environment and Teleoperator Systems), Pisa, Italy, 18-20 March, 2005.
 Chair and Organizer, Annual Symposium on Haptic Interfaces for Virtual Environment and Teleoperator Systems, Atlanta, Nov. 1996; Dallas, Nov. 1997; and Anaheim, 1998 (with Susan J. Lederman); program committee member, 1999-2008.
 Program Committee, IEEE Intl. Conference on Robotics and Automation, 1994, 1997, 1998, 2005.
 Program Committee, IEEE/RSJ Intl. Conference on Intelligent Robots and Systems (IROS), 2004.
 Program Committee, Second Intl. Symposium on Medical Simulation, 2004.

Program Committee, Intl. Symposium on Surgery Simulation and Soft Tissue Modeling (IS4TM 2003), Juan-Les-Pins, France, June 2003.

Program Committee, IEEE Intl. Conference on Systems, Man, and Cybernetics, Tokyo, 1999.

Program Committee, Frontiers of Engineering Symposium, National Academy of Engineering, Irvine, CA, Nov. 1998.

Academic Visiting and Advisory Committees

Advisory Board, Robotics Engineering (RBE) Program, Worcester Polytechnic Institute, 2018-present.

Advisory Board, Department of Mechanical Engineering and Applied Mechanics, University of Pennsylvania, 2015-present.

Visiting Committee, Department of Mechanical Engineering, Stanford University, 2015-16.

Advisory Board, Centre for Autonomous Systems, University of Technology, Sydney, Australia, 2016-2020.

Visiting Committee, Department of Mechanical and Process Engineering (Maschinenbau und Verfahrenstechnik), Eidgenössische Technische Hochschule (ETH) Zürich, 2006-2007.

Government Panels

Strategic Advisory Board, Engineering and Physical Sciences Research Council – United Kingdom Network for Robotics and Autonomous Systems (EPSRC UK-RAS), 2015 – 2020.

Funding Review Panel Member, National Science Foundation, 1994, 2000, 2010, 2014, 2017, 2021, 2022.

DARPA Information Science and Technology (ISAT) Study Group, 2008-2011.

Study section, National Institutes of Health, 2003, 2005.

PUBLICATIONS

Journal Articles

104. Moradi Dalvand M, Nahavandi S, Howe RD, "General Forward Kinematics for Tendon-Driven Continuum Robots," *IEEE Access* **10**:60330-40, 2022
103. Teeple CB, Aktaş B, Yuen MC, Kim GR, Howe RD, Wood RJ, "Controlling Palm-Object Interactions Via Friction for Enhanced In-Hand Manipulation," *IEEE Robotics and Automation Letters* **7**(2):2258-65, 2022. Also presented at the IEEE International Conference on Robotics and Automation, Philadelphia, 2022.
102. Degirmenci A, Howe RD, Perrin DP. "Gaussian Process Regression for Ultrasound Scanline Interpolation. *Journal of Medical Imaging* **9**(3):037001, 2022.
101. Nuckols RW, Lee S, Swaminathan K, Orzel D, Howe RD, Walsh CJ, "Individualization of exosuit assistance based on measured muscle dynamics during versatile walking," *Science Robotics* **6**(60):eabj1362, 2021.
100. Aktaş B, Narang YS, Vasios N, Bertoldi K, Howe RD. "A Modeling Framework for Jamming Structures," *Advanced Functional Materials* **31**(16):2007554, 2021.
99. Narang YS, Aktaş B, Ornellas S, Vlassak JJ, Howe RD, "Lightweight Highly Tunable Jamming-Based Composites," *Soft Robotics* **7**(6):724-35, 2020.
98. Moradi Dalvand M, Nahavandi S, Howe RD, "Slack and Excessive Loading Avoidance in n -tendon Continuum Robots," *IEEE Access* **8**:138730-138742, 2020.
97. Loschak PM, Degirmenci A, Tschabrunn CM, Anter E, Howe RD, "Automatically Steering Cardiac Catheters In Vivo with Respiratory Motion Compensation," *International Journal of Robotics Research* **39**(5): 586-97, 2020.
96. Cheng S, Narang YS, Yang C, Suo Z, Howe RD, "Stick-on large-strain sensors for soft robots," *Advanced Materials Interfaces* **6**(20):1900985, 2019.
95. Moradi Dalvand M, Nahavandi S, Howe RD, "An Analytical Tension Model for Continuum Robots with n Generally Positioned Tendons," *Journal of Medical Robotics Research* **4**(03n04):1942003, 2019.
94. Yamada D, Degirmenci A, Howe RD, "Ultrasound imaging characterization of soft tissue dynamics of the seated human body," *Journal of Biomechanical Engineering* **142**(6), 2020.
93. Vasios N, Narang Y, Aktas B, Howe R, Bertoldi K. "Numerical analysis of periodic laminar and fibrous media undergoing a jamming transition," *European Journal of Mechanics-A/Solids* **75**: 322-329, 2019.
92. Degirmenci A, Perrin DP, Howe RD, "High dynamic range ultrasound imaging," *International Journal of Computer Assisted Radiology and Surgery* **13**(5):721-9, 2018. Also presented at the 9th International Conference on Information Processing in Computer-Assisted Interventions, Berlin, June 20-21, 2018. Winner, Best Paper Award.
91. Gaffney LP, Loschak PM, Howe RD, "A Deployable Transseptal Brace for Stabilizing Cardiac Catheters," *Journal of Mechanical Design* **140**(7):075003, 2018.
90. Moradi Dalvand M, Nahavandi S, Fielding M, Mullins J, Najdovski Z, Howe RD, "Modular Instrument for a Haptically-Enabled Robotic Surgical System (HeroSurg)," *IEEE Access* **6**: 31974-82, 2018.
89. Moradi Dalvand M, Nahavandi S, Howe RD, "An Analytical Loading Model for n -Tendon Continuum Robots," *IEEE Transactions on Robotics* **34**(5):1215-25, 2018.
88. Narang YS, Degirmenci A, Vlassak JJ, Howe RD, "Transforming the Dynamic Response of Robotic Structures and Systems Through Laminar Jamming," *IEEE Robotics and Automation Letters*

- 3(2):688-95, 2018. Also presented at the IEEE International Conference on Robotics and Automation, Brisbane, Australia, May 2018.
87. Wan Q, Howe RD. "Modeling the Effects of Contact Sensor Resolution on Grasp Success." *IEEE Robotics and Automation Letters* 3(3): 1933-1940, 2018. Also presented at the IEEE International Conference on Robotics and Automation, Brisbane, Australia, May 2018.
 86. Yashraj S. Narang, Joost J. Vlassak, and Robert D. Howe, "Mechanically Versatile Soft Machines Through Laminar Jamming," *Advanced Functional Materials* 28(17):1707136, 2018.
 85. Villard P, Hammer P, Perrin D, Del Nido P, Howe, R, "Fast Image-Based Mitral Valve Simulation from Individualized Geometry," *International Journal of Medical Robotics and Computer Assisted Surgery* 14(2):e1880, April 2018.
 84. Gafford J, Ranzani T, Russo S, Degirmenci A, Kesner S, Howe R, Wood R, Walsh C., "Toward Medical Devices with Integrated Mechanisms, Sensors, and Actuators via Printed-Circuit MEMS." *Journal of Medical Devices* 11(1):011007, 2017.
 83. Guggenheim JW, Jentoft LP, Tenzer Y, Howe RD, "Robust and Inexpensive 6-Axis Force-Torque Sensors using MEMS Barometers," *IEEE Transactions on Mechatronics* 22(2): 838-44, 2017.
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 80. Loschak PM, Tenzer Y, Degirmenci A, Howe RD, "A 4-DOF Robot for Positioning Ultrasound Imaging Catheters." *ASME Journal of Mechanisms and Robotics* 8(5):0510161-510169, 2016.
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 76. Odhner LU, Jentoft LP, Claffee MR, Corson N, Tenzer Y, Ma RR, Buehler M, Kohout R, Howe RD, Dollar AM, "A compliant, underactuated hand for robust manipulation," *International Journal of Robotics Research* 33(5):736-752, 2014.
 75. Kesner S, Howe R, "Robotic catheter cardiac ablation combining ultrasound guidance and force control," *International Journal of Robotics Research* 33 (4): 631-644, 2014.
 74. Chen L, Bavigadda V, Kofidis T, Howe RD, "Fiber optic projection-imaging system for shape measurement in confined space," *Scientific World Journal*, Article ID 206569, 2014.
 73. Tenzer Y, Jentoft LP, Howe RD, "The Feel of MEMS Barometers: Inexpensive and Easily Customized Tactile Array Sensors," *IEEE Robotics and Automation Magazine* 21(3):89-95, 2014.
 72. Bowthorpe M, Tavakoli M, Becher H, Howe, R, "Smith Predictor Based Robot Control in Teleoperated Image-guided Beating-heart Surgery," *IEEE Journal of Biomedical and Health Informatics* 18(1): 157-166, 2014.
 71. Hammond FL, Talbot SG, Wood RJ, Howe RD. "Measurement System for the Characterization of Micro-Manipulation Motion and Force." *Journal of Medical Devices* 7(3): 030940, 2013.
 70. Yuen SG, Nikolay VV, del Nido PJ, Howe RD, "Robotic Tissue Tracking for Beating Heart Mitral Valve Surgery," *Medical Image Analysis* 17(8): 1236-1242, 2013.
 69. Schneider RJ, Perrin DP, Vasilyev NV, Marx GR, Del Nido PJ, Howe RD, "Real-time image-based rigid registration of three-dimensional ultrasound," *Medical Image Analysis* 16(2):402-14, 2012.

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67. Schneider RJ, Perrin DP, Vasilyev NV, Marx GR, del Nido PJ, Howe RD, "Mitral annulus segmentation from four-dimensional ultrasound using a valve state predictor and constrained optical flow," *Medical Image Analysis* **16**(2):497-504, 2012.
66. Dollar AM, Howe RD, "Joint Coupling Design of Underactuated Hands for Unstructured Environments," *International Journal of Robotics Research*, 30(9):1157-1169, 2011.
65. Kesner SB and Howe RD, "Design Principles for the Rapid Prototyping of Forces Sensors using 3D Printing," *IEEE/ASME Transactions on Mechatronics* **16**(5):866-870, 2011.
64. Kesner SB and Howe RD, "Position Control of Motion Compensation Cardiac Catheters," *IEEE Transactions on Robotics* **27**(6):1045-1055, 2011.
63. Hammer PE, Sacks MS, del Nido PJ, Howe RD, "Mass-Spring Model for Simulation of Heart Valve Tissue Mechanical Behavior," *Annals of Biomedical Engineering* **39**(6):1668-1679, 2011
62. Jordan P, Kerdok AE, Howe RD, and Socrate S, "Identifying a Minimal Rheological Configuration: A Tool for Effective and Efficient Constitutive Modeling of Soft Tissues," *Journal of Biomechanical Engineering* 133(4):041006, April 2011.
61. Yip MC, Tavakoli M, Howe RD, "Performance Analysis of a Haptic Telemanipulation Task under Time Delay," *Advanced Robotics* **25**(5): 651-673, 2011.
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58. Schneider RJ, Perrin DP, Vasilyev NV, Marx GR, del Nido PJ, Howe RD, "Mitral annulus segmentation from 3D ultrasound using graph cuts," *IEEE Transactions on Medical Imaging* **29**(9):1676-87, 2010.
57. Dollar AM, Howe RD, "The Highly Adaptive SDM Hand: Design and Performance Evaluation," *International Journal of Robotics Research* **29**(5):585–597, 2010.
56. Yip MC, Yuen SG, Howe RD, "A Robust Uniaxial Force Sensor for Minimally Invasive Surgery," *IEEE Transactions on Biomedical Engineering* **57**(5):1008-11, 2010.
55. Rudoy D, Yuen S, Howe RD, Wolfe PJ, "Bayesian changepoint analysis with application to atomic force microscopy and soft material indentation," *Journal of the Royal Statistical Society Series C* **59**(4):573-593, 2010.
54. Dollar AM, Jentoft LP, Gao JH, Howe RD, "Contact sensing and grasping performance of compliant hands" *Autonomous Robotics* **28**(1):65-75, 2010.
53. Perrin DP, Vasilyev NV, Novotny P, Stoll J, Howe RD, Dupont P, Salgo, del Nido PJ, "Image Guided Surgical Interventions," *Current Problems in Surgery* **46**(9): 730-766, 2009.
52. Beasley RA and Howe RD, "Increasing accuracy in image-guided robotic surgery through tip tracking and model-based flexion correction," *IEEE Transactions on Robotics* **25**(2):292-302, 2009.
51. Yuen SG, Kettler DT, Novotny PM, Plowes RD, and Howe RD, "Robotic Motion Compensation for Beating Heart Intracardiac Surgery," *International Journal of Robotics Research* **28**(10): 1355-1372, 2009.
50. Tavakoli M and Howe RD, "Haptic Effects of Surgical Teleoperator Flexibility," *International Journal of Robotics Research* **28**(10):1289-1302, 2009.
49. Balasubramanian R, Howe RD, Matsuoka Y, "Task Performance is Prioritized Over Energy Reduction," *IEEE Transactions on Biomedical Engineering* **56**(5):1310-7, 2009.

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47. Vasilyev NV, Novotny PM, Martinez JF, Loyola H, Salgo IS, Howe RD, del Nido PJ. "Stereoscopic Vision Display Technology in Real-Time Three-Dimensional Echocardiography-Guided Intracardiac Beating-Heart Surgery." *Journal of Thoracic and Cardiovascular Surgery* **135**(6):1334-41, 2008.
46. Nakatani M, Howe RD, Tachi S, "Tactile depth perception examined by the Fishbone Tactile Illusion," *Transactions of the Virtual Reality Society of Japan* **13**(1): 97-100, 2008 (in Japanese).
45. Linguraru MG, Vasilyev NV, Marx GM, Tworetzky W, del Nido PJ, Howe RD, "Fast Block Flow Tracking of Atrial Septal Defects in 4D Echocardiography," *Medical Image Analysis* **12**(4):397-412, 2008.
44. Diamond SG, Davis OC, Howe RD, "Heart rate variability as a quantitative measure of trance depth," *International Journal of Clinical and Experimental Hypnosis* **56**(1):1-18, 2008.
43. Novotny PM, Stoll JA, Vasilyev NV, Del Nido PJ, Dupont PE, Howe RD, "GPU Based Real-time Instrument Tracking with Three Dimensional Ultrasound," *Medical Image Analysis* **11**(5):458-64, 2007. NIHMSID 31449
42. Linguraru MG, Kabla A, Marx GR, del Nido PJ, Howe RD, "Real-Time Tracking and Shape Segmentation of Atrial Septal Defects in 3D Echocardiography," *Academic Radiology* **14**:1298-1309, 2007.
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39. Wagner CR, Stylopoulos N, Jackson PG, Howe RD, "The Benefit of Force Feedback in Surgery: Examination of Blunt Dissection," *Presence* **16**(3): 252-262, June 2007.
38. Novotny PM, Jacobsen SK, Vasilyev NV, Kettler DT, Salgo IS, Dupont PE, del Nido PJ, and Howe RD, "3D ultrasound in robotic surgery: performance evaluation with stereo displays," *International Journal of Medical Robotics and Computer Assisted Surgery*, **2**(3):279-285, 2006.
37. Diamond SG, Davis OC, Schaechter JD, Howe RD, "Hypnosis for Rehabilitation after Stroke: Six Case Studies," *Contemporary Hypnosis* **23**(4), 173-180, 2006.
36. Kerdok AE, Ottensmeyer MP and Howe RD, "The effects of perfusion on the viscoelastic characteristics of liver," *Journal of Biomechanics* **39**(12):2221-31, 2006.
35. Dollar AM and Howe RD, "A Robust Compliant Grasper via Shape Deposition Manufacturing," *IEEE/ASME Transactions on Mechatronics* **11**(2):154-161, April 2006.
34. Suematsu Y, Martinez JF, Wolf BK, Marx GR, Stoll JA, DuPont PE, Howe RD, Triedman JK, del Nido PJ. "Three-dimensional echo-guided beating heart surgery without cardiopulmonary bypass: atrial septal defect closure in a swine model," *Journal of Thoracic and Cardiovascular Surgery* **130**(5):1348-57, November 2005.
33. Gunter HE, Howe RD, Zeitels SM, Kobler JB, Hillman RE, "Measurement of vocal fold collision forces during phonation: Methods and preliminary data" *Journal of Speech, Language, and Hearing Research* **48**(3):567-76, June 2005.
32. Dollar AM, Howe RD, "Towards grasping in unstructured environments: Grasper Compliance and Configuration optimization," *Advanced Robotics*, **19**(5):523-543, June 2005.
31. T.J. Debus P.E. Dupont, and R.D. Howe, "Distinguishability and Identifiability Testing of Contact State Models," *Advanced Robotics*, **19**(5):545-566, June 2005.

30. Samosky J, Burstein D, Grimson WE, Howe R, Martin S, Gray ML. Spatially-localized correlation of dGEMRIC-measured GAG distribution and mechanical stiffness in the human tibial plateau *Journal of Orthopedic Research* **23**(1):93-101, January 2005.
29. Suematsu Y, Marx GR, Stoll JA, DuPont PE, Cleveland RO, Howe RD, Triedman JK, Mihaljevic T, Mora BN, Savord BJ, Salgo IS, del Nido PJ, "Three-dimensional echocardiography-guided beating-heart surgery without cardiopulmonary bypass: a feasibility study," *Journal of Thoracic and Cardiovascular Surgery* **128**(4):579-87, October 2004.
28. T. Debus, T.-J. Jang, P. Dupont, and R. Howe, "Multi-Channel Vibrotactile Display for Teleoperated Assembly," *International Journal of Control, Automation & Systems* **2**(3):390-397, September 2004.
27. C.R. Wagner, S.J. Lederman, R.D. Howe, "Design and Performance of a Tactile Shape Display Using RC Servomotors," *Haptics-e* **3**(4), August 2004.
26. T.J. Debus, P.E. Dupont, and R. D. Howe, "Contact State Estimation using Multiple Model Estimation and Hidden Markov Models," *International Journal of Robotics Research* **23**(4-5):399-413, April-May 2004.
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19. Pawluk, D.T.V. and Howe, R. D. "Dynamic contact of the human fingerpad against a flat surface." *ASME Journal of Biomechanical Engineering* **121**(6):605-611, December 1999.
18. P. Dupont, T. Schulteis, P. Millman, and R. D. Howe, "Automatic Identification of Environment Haptic Properties," *Presence* **8**(4):392-409, August 1999.
17. Pawluk, D.T.V. and Howe, R. D. "Dynamic Lumped Element Response of the Human Fingerpad." *ASME Journal of Biomechanical Engineering* **121**(2):178- 184, April 1999.
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14. A.Z. Hajian and R.D. Howe, "Identification of the mechanical impedance at the human finger tip," *ASME Journal of Biomechanical Engineering*, 119(1):109-114, Feb. 1997. Also presented at the International Mechanical Engineering Congress, American Society of Mechanical Engineers, Chicago, IL, November 1994, Proceedings ed. C. J. Radcliffe, DSC-vol. 55-1, p. 319-327.
13. R. D. Howe and M. R. Cutkosky, "Practical force-motion models for sliding manipulation," *International Journal of Robotics Research* **15**(6):557-572, December 1996.

12. J. S. Son, M. R. Cutkosky, and R. D. Howe, "Comparison of contact sensor localization abilities during manipulation," *Robotics and Autonomous Systems*, **17**(4):217-233, June 1996. Also presented at IROS '95: IEEE/RSJ International Conference on Intelligent Robots and Systems, Pittsburgh, PA, August 5-9, 1995, Proceedings vol. 2, p. 96-101.
11. D. A. Kontarinis and R. D. Howe, "Tactile display of vibratory information in teleoperation and virtual environments," *Presence*, **4**(4):387-402, 1995.
10. R. D. Howe, W. J. Peine, D. A. Kontarinis, and J. S. Son, "Remote palpation technology," *IEEE Engineering in Medicine and Biology*, **14**(3):318-323, May/June 1995.
9. R. D. Howe, "Tactile sensing and control of robotic manipulation," *Journal of Advanced Robotics*, **8**(3):245-261, 1994.
8. R. D. Howe and M. R. Cutkosky, "Dynamic tactile sensing: Perception of fine surface features with stress rate sensing," *IEEE Transactions on Robotics and Automation* **9**(2):140-151, April 1993.
7. B. Edin, R. D. Howe, G. Westling, and M. R. Cutkosky, "A physiological method for relaying frictional information to a human teleoperator," *IEEE Transactions on System, Man, and Cybernetics*, **23**(2):427-432, March/April 1993.
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1. G. Kychakoff, R. D. Howe, R. K. Hanson, and J. C. McDaniel, "Quantitative visualization of combustion species in a plane," *Applied Optics* **21**:3225-3227, September 15, 1982.

Refereed Conference Papers

126. Koenig A, Liu Z, Janson L, Howe R, "The Role of Tactile Sensing in Learning and Deploying Grasp Refinement Algorithms," *Proceedings of the IEEE/RSJ Int. Conf. on Intelligent Robots and Systems (IROS)*, October 23–27, 2022, Kyoto, Japan.
125. B. Aktaş and R. D. Howe, "Tunable Anisotropic Stiffness with Square Fiber Jamming," *Proceedings of the 3rd IEEE International Conference on Soft Robotics (RoboSoft)*, New Haven, CT, USA, 2020, pp. 879-884.
124. Ouyang R, Howe R. "Low-Cost Fiducial-based 6-Axis Force-Torque Sensor," *Proceedings of the IEEE International Conference on Robotics and Automation*, May 31, 2020, pp. 1653-1659.

123. Nuckols RW, Swaminathan K, Lee S, Awad L, Walsh CJ, Howe RD, "Automated detection of soleus concentric contraction in variable gait conditions for improved exosuit control," *Proceedings of the IEEE International Conference on Robotics and Automation*, May 31, 2020, pp. 4855-4862.
122. Aktas B, Howe RD, "Flexure Mechanisms with Variable Stiffness and Damping Using Layer Jamming", *Proceedings of the IEEE/RSJ Int. Conf. on Intelligent Robots and Systems (IROS)*, Macau, China, November 3-7 2019.
121. Swaminathan K, Lee S, Nuckols RW, Revi DA, Singh P, Howe RD, Smith MA, Walsh CJ, "Biomechanics Underlying Subject-Dependent Variability in Motor Adaptation to Soft Exosuit Assistance," In Masia L, Micera S, Akay M, Pons J (eds), *Converging Clinical and Engineering Research on Neurorehabilitation III. Proc. International Conference on NeuroRehabilitation*, Pisa, Italy, Oct. 2018, Biosystems & Biorobotics vol 21, Springer, Cham.
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Patents

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- S. Cheng, Y. Narang, C. Yang, Z. Suo, R. Howe, "Composite materials," US Patent application no. 16/872,088, filed May 11, 2020.
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"Modeling by Manipulation" *Video proceedings of the IEEE International Conference on Robotics & Automation*, New Orleans, April, 2004.

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R. D. Howe and R. E. Kronauer, "Thomas McMahon: A Dedication In Memoriam," *Annual Review of Biomedical Engineering* vol. 3, 2001.

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Invited testimony, Hearing on the Future of Research-Intensive Universities and Their Relationship with the Federal Government, President's Council of Advisors on Science and Technology, Dr. D. Allan Bromley, Chair, Massachusetts Institute of Technology, June 24, 1992.

Expert Witness Experience: Depositions, Trial Testimony, and IPR Declarations

Robert D. Howe

January 2023

Restore Robotics LLC and Restore Robotics Repair LLC v. Intuitive Surgical, Inc.

No. 5:19-cv-55-TKW-MJF, Northern District of Florida

Testified at deposition for Intuitive Surgical (defendant, represented by Skadden, Arps, Slate, Meagher & Flom LLP). October 2021.

Rebotix Repair LLC v. Intuitive Surgical, Inc.

No. 8:20-cv-2274-T-33TGW, Middle District of Florida

Testified at deposition for Intuitive Surgical (defendant, represented by Skadden, Arps, Slate, Meagher & Flom LLP). October 2021.

Rex Medical, L.P. v. Intuitive Surgical, Inc.

No. 19-cv-00005-MN, District of Delaware

Testified at deposition and trial for Intuitive Surgical (defendant, represented by Winston & Strawn). Tried October 2022.

Ethicon LLC v. Intuitive Surgical, Inc.

No. 17-871-LPS-CJB, District of Delaware

Testified at ITC evidentiary hearing for Intuitive Surgical (defendant, represented by Kecker, Van Nest & Peters). Feb. 2021.

Immersion Corporation v. Samsung Electronics America, Inc. and Samsung Electronics Co., Ltd.

No. 2:17-cv-00572-JRG, Eastern District of Texas

Testified at deposition for Immersion Corporation (plaintiff, represented by Morrison & Foerster). 2018-2019.

Immersion Corporation v. Motorola Mobility LLC and Motorola Mobility Holdings LLC

No. 17-1081-RGA, District of Delaware

Testified at deposition for Immersion Corporation (plaintiff, represented by Morrison & Foerster). 2018-2019.

Zenimax Media Inc. and Id Software LLC v. Oculus VR LLC, Facebook Inc., et al.

No. 3:14-CV-01849, Northern District of Texas

Testified at deposition and trial for Oculus VR LLC, Facebook Inc., et al. (defendants, represented by Cooley), tried January 2017.

Appendix B

List of Materials Considered

Produced Documents

(In re: da Vinci Surgical Robot Antitrust Litigation, Case No. 3:21-cv-03825-VC and Surgical Instrument Service Co. v. Intuitive Surgical, Inc., Case 3:21-cv-03496-VC):

- Intuitive-00004685
- Intuitive-00004692
- Intuitive-00008958
- Intuitive-00010744
- Intuitive-00010745
- Intuitive-00027876
- Intuitive-00043879
- Intuitive-00104966
- Intuitive-00223998
- Intuitive-00290857
- Intuitive-00369329
- Intuitive-00477154
- Intuitive-00477217
- Intuitive-00477325
- Intuitive-00477422
- Intuitive-00477597
- Intuitive-00477620
- Intuitive-00477757
- Intuitive-00477829
- Intuitive-00477958
- Intuitive-00478097
- Intuitive-00537574
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- Intuitive-00603411
- Intuitive-00620947
- Intuitive-00626429
- Intuitive-00626673
- Intuitive-00695006
- Intuitive-00705141
- Intuitive-00705143
- Intuitive-00705155
- Intuitive-00705253
- Intuitive-00705351
- Intuitive-00705406
- Intuitive-00705431
- Intuitive-00705438
- Intuitive-00705453
- Intuitive-00784474
- Intuitive-01085065
- Intuitive-01085533

Produced Documents (Restore/Rebotix):

- ACG000006
- AHP000369
- AHP000373
- AHP000404
- AHP000525
- AHP000527
- AHP000658
- AHP000706
- AHP000708
- AHP000729
- AHP000732
- AHP000803

- AHP000832
- AHP000928
- AHP000939
- AHP002062
- AHP002130
- AHP002395
- AHP002448
- AHP002623
- AHP002680
- AHP003709
- AHP005099
- AHS_HMC-INTUITIVE_0000039
- AHS_MGMT000007
- AHS_MGMT-INTUITIVE_0000312
- AHS_MGMT-INTUITIVE_0000313
- AHS_MGMT-INTUITIVE_0000603
- BB000011
- BPI000331
- BSWH-0000221
- BSWH-0000255
- CRMC
- Intuitive-00552744
- Intuitive-00552745
- REBOTIX000365
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- Restore-00132592

Deposition Transcripts and Exhibits

(In re: da Vinci Surgical Robot Antitrust Litigation, Case No. 3:21-cv-03825-VC and Surgical Instrument Service Co. v. Intuitive Surgical, Inc., Case 3:21-cv-03496-VC):

- Duque, Grant 30(b)(6) (Nov. 8, 2022) and Exhibits
- Goodson, Nickola (Oct. 27, 2022) and Exhibits
- Hamilton, Stan (Nov. 4, 2022) and Exhibits
- Johnson, Keith (Oct. 27, 2022) (individual testimony) and Exhibits
- Johnson, Keith 30(b)(6) (Oct. 27, 2022) and Exhibits
- May, Kevin (Nov. 3, 2022) and Exhibits
- Parker, Clifton (Oct. 25, 2022) and Exhibits
- Peswani, Disha (Oct. 6, 2022) and Exhibits
- Posdal, Greg (Nov. 1, 2022) (individual testimony) and Exhibits
- Posdal, Greg 30(b)(6) (Nov. 1, 2022) and Exhibits
- Somayaji, Sharathchandra (Nov. 4, 2022) and Exhibits

Deposition Transcripts and Exhibits

(Restore Robotics LLC v. Intuitive Surgical, Inc., Case No. 5:19-cv-55-TKW-MJF):

- Gordon, West (May 13, 2021) and Exhibits
- May, Kevin (May 6, 2021) and Exhibits
- May, Kevin (June 8, 2021) and Exhibits
- Parker, Clifton (May 4, 2021) and Exhibits
- Vautrot, Mills (May 11, 2021) and Exhibits

Expert Reports

(In re: da Vinci Surgical Robot Antitrust Litigation, Case No. 3:21-cv-03825-VC)

- Expert Report of Professor Einer Elhauge (Dec. 1, 2022)
- Expert Report of Dr. Eugene Rubach (Dec. 1, 2022)
- Expert Report of Kimberly A. Trautman, MS (Dec. 1, 2022)

Expert Reports

(Surgical Instrument Service Co. v. Intuitive Surgical, Inc., Case 3:21-cv-03496-VC)

- Expert Report of Richard F. Bero (Dec. 2, 2022)

- Expert Report of Dr. Russel L. Lamb (Dec. 2, 2022)
- Expert Report of Amandeep Mahal, MD (Dec. 1, 2022)
- Expert Report of Philip J. Philips (Dec. 2, 2022)

Court Documents

(In re: da Vinci Surgical Robot Antitrust Litigation, Case No. 3:21-cv-03825-VC)

- Consolidated Class Action Complaint (ECF. No 52)
- Defendant Intuitive Surgical, Inc.’s Answer and Affirmative Defense (ECF 74)
- Plaintiff Franciscan Alliance, Inc.’s Amended Objections and Responses to Defendant’s Second Set of Interrogatories to Plaintiffs (Sept. 30, 2022)
- Plaintiff Larkin’s Amended Objections and Responses to Defendant’s Second Set of Interrogatories to Larkin (Sept. 30, 2022)
- Plaintiff Valley Medical Center’s Amended Objections and Responses to Defendant’s Second Set of Interrogatories to Plaintiffs (Sept. 30, 2022)
- Plaintiff Franciscan Alliance, Inc.’s Objections and Responses to Defendant’s Requests for Admissions to Plaintiff (Nov. 16, 2022)
- Plaintiff Larkin Community Hospital’s Objections and Responses to Defendant’s Requests for Admissions to Plaintiff (Nov. 16, 2022)
- Plaintiff Valley Medical Center’s Objections and Responses to Defendant’s Requests for Admissions to Plaintiff (Nov. 16, 2022)

Court Documents

(Surgical Instrument Service Co. v. Intuitive Surgical, Inc., Case 3:21-cv-03496-VC):

- SIS Complaint (ECF No. 1)
- Defendant Intuitive Surgical, Inc.’s Answer, Affirmative Defenses, and Counterclaims (ECF No. 75)
- Plaintiff Surgical Instrument Service Company, Inc.’s Answers & Objections to Defendant’s Interrogatories, Second Set Nos. 4-18 (Aug. 8, 2022)

Other Materials:

- “Access and instruments product catalog” Medtronic, 2020, available at: <https://www.medtronic.com/content/dam/covidien/library/us/en/product/handinstruments-and-ligation/access-instrumentation-products-catalog.pdf>.
- Anderson, James M., Analiz Rodriguez, and David T. Chang. “Foreign body reaction to biomaterials,” in *Seminars in Immunology*, vol. 20, no. 2, pp. 86-100, 2008
- August 19, 2021 Conversation with Ron Bair
- da Vinci S and Si Instrument Reprocessing Instructions for Automated Cleaning and Disinfection, https://manuals.intuitivesurgical.com/c/document_library/get_file?uuid=d237e175-3fce-3844-863e-37e733afe0d6&groupId=73750789
- da Vinci Xi Instrument Reprocessing Instructions for Automated Cleaning and Disinfection,

https://manuals.intuitivesurgical.com/c/document_library/get_file?uuid=b1b9f169-4503-9ea9-6db9-9243c28d5221&groupId=73750789

- Def.’s Ex. 135 (Defendant Intuitive Surgical Inc.’s Notice of Deposition of Plaintiff Surgical Instrument Service Company, Inc. Pursuant to Fed. R. Civ. P. 30(b)(6))
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